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An examination of the contribution of clinical and psychological factors to treatment decision-making capacity in psychosis.

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Contents

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Acknowledgements

Firstly, I would like to thank all the participants who took part in this research. It was a humbling experience and a privilege to meet you all and talk to you about your experiences.

I am grateful to the clinicians and mental health teams who helped me with recruiting to the study, in both NHS Dumfries and Galloway, and NHS Lothian.

This thesis would not have been possible without the support of my supervisor, Dr. Paul Hutton, who went above and beyond what would have been expected of a thesis supervisor. Being able to be part of a larger group of researchers with an interest in decisional capacity in psychosis, has added meaning to this work, and being involved in a wider discussion about treatment decision making capacity has deepened my understanding of this complex area.

I am also grateful for the support of my family and friends throughout the last three years. You have all been generous with your time, supportive, and understanding and I hope to be able to be as supportive to you all in the future.

I would like to dedicate this thesis to my brother, Derek, who died tragically just before I started the Doctorate. He was a role model to me while he was alive, and his death has continued to give me new perspectives on life. I hope that he would be proud of what I have managed to achieve since his death.

List of tables and figures

Overview of thesis

This thesis follows the portfolio format and the following information provides a brief summary of the main chapters of the thesis:

Chapter 1 is a systematic review and meta-analysis of the research literature exploring the risk factors and correlates of impaired treatment decision making capacity in people who have experienced psychosis. Chapter 2 presents a research journal article which explores the role of cognitive biases in the treatment decision making capacity of people who have experienced psychosis. The thesis portfolio concludes with a complete reference list for the whole thesis and an appendix section, which allows the reader to access extra information related to the research process.

The systematic review and empirical journal article were written for submission to the Journal of Clinical Psychology. The author guidelines for this journal are included in Appendix J.

Thesis Abstract

Purpose: A systematic review and meta-analysis was conducted to identify what factors have been investigated as correlates of the 4 key domains of treatment decision making capacity (TDMC) in people who have experienced psychosis (understanding, reasoning, appreciation, communication) and to provide estimates of the magnitude of these correlations, taking into account study quality. A novel empirical study was conducted to test the hypothesis that variance in psychosis-specific cognitive biases (including the well-established 'jumping to conclusions' bias) would account for unique variance in TDMC domains in those with psychosis, after taking into account the known contribution of symptoms and insight. A secondary aim of the empirical study was to examine for the first time the relationship between TDMC and personal recovery in this group, and post hoc analyses of the relationship between cognitive biases, emotional distress and TDMC were also conducted.

Methods: Electronic databases were systematically searched for literature on the schizophrenia and psychosis and treatment decision making capacity. Pooled estimates of correlation were estimated for factors with data from three or more studies, and both study and outcome quality were systematically assessed. A cross-sectional observational study was conducted, and individuals with psychosis completed measures of TDMC, cognitive biases, psychotic symptoms and recovery. Multiple regression was used to examine the primary and secondary hypotheses, and mediation analyses were used to conduct the post hoc analyses. Additional data from a parallel study was incorporated to increase power.

Results: Twenty-four studies met inclusion criteria for the systematic review and meta-analysis. Low to moderate quality evidence suggested that the ability of people with psychosis to understand treatment-relevant information was strongly associated with overall psychotic symptom severity, verbal cognitive functioning and years of education, but not depression (moderate quality evidence). Low quality evidence suggested reasoning was strongly associated with verbal cognitive functioning and moderately associated with symptoms. Appreciation was associated with symptoms, but it and communication were generally poorly studied. Findings from the empirical study suggest that cognitive biases, and the Jumping to Conclusions bias in particular, predicts a moderate amount of the variance in the understanding and reasoning TDMC domains, but did not add predictive power to a model containing symptoms, insight, and cognition. The appreciation domain was strongly predicted by cognitive biases, insight, and cognition. TDMC was not found to be correlated with personal recovery and post hoc analyses did not find that emotional distress mediated any relationship between cognitive biases and TDMC.

Conclusions: The meta-analysis confirms there is a robust association between symptoms and TDMC in psychosis, as currently conceived. The empirical study suggests cognitive biases may be related to TDMC, even after taking into account the contribution of symptoms. Larger studies, perhaps employing experimental procedures, are required to clarify the exact nature of this relationship. The lack of any relationship between TDMC and service-user defined recovery from psychosis is notable, and lends support to those calling for a conceptualisation of TDMC that takes greater account of this concept.

Chapter 1: Systematic review and meta-analysis

Treatment decision making capacity in psychosis: A systematic review and meta-analysis of correlates, risk factors and treatment effects.

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Abstract

Objectives: To improve our theoretical understanding of treatment decision-making capacity (TDMC) in psychosis, we did a systematic review and meta-analysis to identify risk factors associated with impairment, taking into account the quality of the literature.

Method: We searched EMBASE, Medline and PsycInfo for relevant studies. For each potential correlate that had been examined, we computed standardised effect sizes and 95% confidence intervals, and presented these within an assessment of study quality. Random-effects meta-analyses were conducted when there were at least 3 relevant studies, with the quality of the estimates assessed using GRADE.

Results: Twenty-four relevant studies were identified, providing data from 1,823 participants with psychosis. Low to moderate quality evidence suggested that the ability of people with psychosis to understand treatment-relevant information was strongly associated with overall psychotic symptom severity, verbal cognitive functioning and years of education, but not depression (moderate quality evidence). Low quality evidence suggested TDMC-related reasoning ability was strongly associated with verbal cognitive functioning and moderately associated with symptoms. The appreciation domain had a smaller association with symptoms, but both it and communication domain were generally poorly studied. Emerging evidence identified insight, shorter duration of illness, metacognitive awareness, and use of specific interventions such as altering the presentation of information as factors linked to improved TDMC.

Conclusions: Symptoms, verbal cognitive functioning and duration of education are robustly associated with components of treatment decision-making capacity in psychosis. However, we lack data on the role of cognitive biases, appraisals or wider social factors such as stigma, and only two randomised controlled trials have tested strategies to support decision-making capacity.

Key words: Schizophrenia; psychosis; treatment decision making-capacity; capacity; competence.

Introduction

Capacity is a term that has its origins in legislation, but has become increasingly relevant to clinical practice. In the Adults with Incapacity (Scotland) Act (2000), a judgment of incapacity is justified when the following conditions are met: that the person is incapable of (a) acting; or (b) making decisions; or (c) communicating decisions; or (d) understanding decisions; or (e) retaining the memory of decisions. Research in the area of decision-making capacity has centred on a model of capacity defined by Appelbaum and Grisso (1995) which defined capacity in terms of four abilities; ability to communicate a choice, ability to understand relevant information, ability to appreciate the situation and ability to manipulate information rationally (i.e., the ability to reason). This model fits with the legal definition of capacity to make decisions in the United Kingdom (Mental Capacity Act, 2005; Adults with Incapacity (Scotland) Act, 2000), and focuses on the person's ability to understand and apply information relating to the specific decision to be made.

Capacity has become an increasingly important concept in mental health care. Under current UK legislation a judgement of impaired treatment decision-making capacity (TDMC) by a healthcare professional can represent the point whereby a person experiences a formal loss of autonomy and accountability in relation to healthcare decisions. The focus on patient autonomy in mental health law in the UK can be traced back to a Department of Health review of Mental Health Law, which stated that:

"The desire to promote non-discrimination on the grounds of mental health has led inevitably to an emphasis on patient autonomy. In the context of physical health a patient with capacity is free to choose whether or not to accept treatment: his or her autonomy is respected" (Department of Health, 1999, p. 18).

Autonomy is protected under human rights legislation, for example Article 12 of the United Nations Convention on the Rights of Persons with Disabilities recognises the right to be recognised as a person before the law, and the subsequent right to have one's decisions legally recognised. Research on recovery in mental health has also found that autonomy and empowerment are key components of people's perceived wellness and recovery (Pitt et al., 2007; Law & Morrison, 2014; SAMHSA, 2008). The Adults with Incapacity (Scotland) Act (2000) requires clinicians to empower patients to make decisions and to make an assumption of capacity until proven otherwise. However, if patients who lack capacity are allowed to make decisions, these may not reflect their true wishes and the consequence may be a poor outcome and inadequate protection of the patient (Lepping, 2011). Capacity has been called the *"gatekeeper for autonomy"* (Donnelly, 2010).

Although the concept of decisional capacity for consent emerged from case law and legislation, and is closely tied to the legal concept of competency, clinicians (often psychiatrists) are usually charged with assessing this (Candia & Barba, 2011). Consultations on decision-making capacity constitute 1 in 6 referrals to psychiatry (Seyfried, Ryan, & Kim, 2013), and a recent systematic review by Lepping, Stanley, & Turner (2015) found that the average percentage of patients with impaired TDMC on psychiatric wards is 45%. A review by Jeste et al. (2006) found between 10% and 52% of people diagnosed with schizophrenia and psychosis were judged to have impaired TDMC. However, despite the frequency with which psychiatrists are asked to make such judgements, almost 50% of them judged the evidence base in this area to be weak (Seyfried, Ryan, & Kim, 2013).

The field of decision-making capacity research has grown in the last number of years. This has been spurred on by changes in legislation, but also by a change in the

culture in which healthcare decisions are made. Users of mental health services are showing a greater desire to be included in decisions about their treatment (Hamann et al., 2005: Hill & Laughrane, 2006). There has been an increasing emphasis on ensuring that not only are patients giving their informed consent to treatment, but also that they are actively involved in the decision making process (NICE, 2011). The most common model for involving patients in decision-making is 'shared decision-making', which involves including the service user as partners in medical and mental health care decision making (Hamann et al., 2003). There is evidence that only a minority of people with psychosis experience this, with only 41% of people surveyed as part of the Second National Audit of Schizophrenia reporting that they felt adequately involved in decisions about medication (Royal College of Psychiatrists, 2014). Since impaired capacity is a major barrier to psychiatrists implementing shared decision-making with people with psychosis (Hamann et al., 2009), improving our understanding of factors that cause or maintain this impairment may help to ensure that greater numbers of patients are involved in a shared decision making process.

British Medical Association (2013) guidance on capacity states that it is the duty of the assessing clinician to enhance capacity where it is possible to do so. In the context of psychiatric and mental health conditions, this is often achieved through treatment of the condition itself; however there has been little research on the effectiveness of current treatment as usual in enhancing decision making capacity. Although some studies have examined whether specific psychological and educational interventions can enhance TDMC (Carpenter et al., 2000; Naughton et al., 2012), these have yet to be systematically reviewed.

Candia & Barba (2011) summarised the current position of research in relation to mental capacity and consent to treatment in psychiatric patients, and concluded that the field is still growing and the literature is often difficult to interpret. Systematic reviews have variously examined the prevalence of incapacity in psychiatric patients (Okai et al. 2007), the reliability and validity of instruments used to assess treatment and research capacity (Dunn et al., 2006; Sturman et al., 2005), the degree of impairment in decisional capacity in schizophrenia (Jeste, Depp, & Palmer, 2006), the relationship between competence and poor insight (Ruissen et al., 2012) and the associations of specific neuropsychological deficits with capacity to consent to treatment or research (Palmer & Salva, 2007). Although one older review examined the correlates of TDMC in psychiatric populations generally (Okai et al., 2007), no reviews have yet looked at the factors associated with TDMC in people with psychosis specifically.

Psychosis is a transdiagnostic term that is used to describe experiences such as hearing voices, holding strong beliefs that others around you do not, difficulties with thinking and concentrating, and emotional changes (BPS, 2014). Research occurs under a paradigm or set of assumptions that is often unconscious (Bentall, 2003). In research on schizophrenia and psychosis, this set of assumptions often includes the assumption that the diagnosis of psychotic disorders is reliable and valid. However, there have been criticisms of the diagnosis of psychotic disorders for many decades now (Bentall, Jackson, & Pilgrim, 1988), with the American Psychiatric Association acknowledging in 1980 that "the limits of the concept of schizophrenia are unclear" (APA, 1980, p.181). Some researchers have argued strongly for a continuum approach as opposed to the traditional categorical approach, for example Van Os and Reininghaus (2016) argue for the existence of an "extended and transdiagnostic

phenotype" of psychosis in the general population. These arguments are based on the acknowledged limitations of diagnosis of psychotic disorders which have been shown to have limited reliablilty and validity. A study by Bromet et al. (2005) found that 93.5% of people in their sample who had received a diagnosis of schizophrenia retained that diagnosis 10 years later, while only 28.6% of people in their sample retained a diagnosis of schizoaffective disorder 10 years later. Using DSM-5 criteria, Regier et al. (2013) found that raters achieved a Cohen's kappa coefficient of 0.39 – 0.50 for schizophrenia and schizoaffective disorder (fair to moderate agreement as defined by Landis & Koch (1977)). The validity of using diagnostic labels for psychotic experiences has been called into question by research which has found that specific psychotic experiences exist on a continuum in the general population (Beavan et al., 2011; vanOs, 2003), that psychotic symptom types are not in themselves strong associates of schizophrenia (Goldman et al., 1992), and that there is considerable overlap between diagnostic categories that are presented in diagnostic frameworks as discrete entities (Reininghaus et al., 2016). In addition there have been several other frameworks proposed for understanding psychotic experiences that do not include an illness or diagnosis framework, for example emancipatory explanations (Romme & Escher, 1989), or psychological explanations (Garety et al., 2001; Morrison, 2001). Most of the research on decision making capacity in people who have experienced psychosis has been carried out with people who have received a diagnosis of schizophrenia or other psychotic disorder using a categorical model under the assumption that these labels are a reliable and valid indicator of the sample having experienced psychosis.

Although people diagnosed with psychotic disorder are more likely than people diagnosed with non-psychotic mental health conditions to be judged to lack TDMC

(Okai et al., 2007; Owen et al., 2009), such a diagnosis is neither necessary nor sufficient for a judgement of decisional incapacity. Jeste et al. (2006) found that the prevalence of incapacity in psychosis varied between 10% and 52%, and published studies demonstrate substantial heterogeneity in incapacity within both psychotic and non-clinical populations (Jeste, Depp, & Palmer, 2006). Nonetheless, some research suggests diagnostic status may moderate the relationship between psychopathological variables and capacity (Candia & Barba, 2011). For example, Owen et al. (2009) found that insight was the best discriminator of capacity status in people diagnosed with psychotic disorders and bipolar disorder, but not in non-psychotic disorders.

In summary, the concept of TDMC has become increasingly relevant to health care professionals and users of mental health services. Identifying those factors that are associated with TDMC in psychosis may help us develop a clinically useful theoretical model, which in turn will aid the development of effective interventions to support capacity. Thus, the primary objective of this systematic review is to identify which clinical and demographic variables are associated with treatment decision-making capacity in psychosis and, where a sufficient number of comparable studies exist, use meta-analysis and a systematic assessment of study and outcome quality to produce pooled estimates of the significance, magnitude and reliability of any relationship.

Method

To minimise the risk of selective reporting bias and maximise transparency, a protocol for the systematic review was registered in advance with the PROSPERO International Prospective Register of Systematic Reviews (Larkin & Hutton, 2015;

registration number: CRD42015025568). The protocol was updated to include a quantitative synthesis of effect sizes using meta-analytic procedures where three or more studies provided usable data, and incorporation of GRADE to assess outcome quality (Guyatt et al., 2008).

Eligibility criteria

As shown in Table 1, studies were included if they were published in English before October 2015, included a reliable and valid assessment of TDMC with adults diagnosed with a non-affective psychotic disorder and provided data on the association between TDMC and at least one other clinical or demographic variable. Assessment of TDMC was accepted as valid if participants had been asked to make a real or hypothetical decision about a health care or treatment decision, and if a valid and reliable tool was used to measure at least one of the accepted domains of decisional capacity: understanding, appreciation, communicating a choice, and retaining the memory of the decision. Any study reporting usable cross-sectional or longitudinal data was eligible for inclusion, regardless of study design. Studies were excluded where the proportion of participants with non-affective psychosis was less than 50% or where TDMC was not measured using a valid or reliable assessment. Since we are specifically investigating correlates of *treatment* decision-making capacity, and because capacity is a decision-specific concept, we excluded studies where only capacity to consent to participate in research or legal proceedings was examined.

Search strategy

A search using the terms (Schizo* OR Psychosis) AND (Capacity OR Decision making OR Consent) AND (Treatment OR Health care) was conducted in the

databases Embase, Embase Classic, Medline, and PsycInfo from 1947 to October 2015. One researcher (AL) conducted the search (with support and training from a qualified librarian), and another (PH) provided supervision and consultation in the case of any uncertainty. The full search strategy is provided in Appendix A. Previous reviews and included studies were hand searched for additional studies, and authors were contacted for any further unpublished studies.

Study selection

The titles and abstracts of studies identified by the search were screened to eliminate obviously irrelevant studies (e.g. studies of unrelated conditions, or other reviews). The full-text reports for any remaining studies were then examined to determine eligibility against the inclusion and exclusion criteria.

Table 1. Inclusion and exclusion criteria

Category	Criteria
Study population	Population consisted of people who had been diagnosed with a non-affective psychotic disorder (ICD-10 F20 – F29 diagnoses). Studies that used a mixed population were included if >50% of the population was people diagnosed with non-affective psychotic disorders.
Study geography	Studies from all countries were accepted if they had used a definition of capacity that included at least one of the four accepted factors in capacity as defined above.

Category	Criteria
Factors / Interventions	Any factors that were measured using a valid measure and had been assessed as contributing to treatment decision-making capacity were included. Baseline and change data from studies of interventions designed to enhance treatment decision-making capacity, or studies which had assessed treatment decision-making capacity pre- and post-intervention were included.
Time period	Studies published between 1947 and October 2015 were included in the review.
Publication language	Studies published in the English language only were included in the review.
Admissible evidence (study design and other criteria)	Case studies and descriptions were excluded from the review.

Quality assessment

In line with previous systematic reviews (Taylor, Hutton and Wood, 2015; Dudley, Taylor, Wickham & Hutton, 2016), the assessment of observational study quality was conducted using an adapted version of the Agency for Healthcare Research and Quality assessment tool (Williams et al., 2010). The adequacy of the methods used to select the cohort, the sample size, the methods used to assess outcomes, the degree of missing data, and the appropriateness of the analytic methods used were all assessed as "yes","no", "partial" or 'can't tell' (see Appendix B). Randomised controlled

trials were assessed using the well-established Cochrane Risk of Bias tool (Higgins & Green, 2011), which assesses risk of selection, performance, detection, attrition and reporting biases (see Appendix C).

An adapted version of GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) (Guyatt et al., 2008) system was used to assess the quality of the effect size estimates, whether derived from single studies or groups of studies. Whether this was judged to be high, moderate, low or very low is based on consideration of overall study quality (as determined by AHRQ ratings) as well as consistency and precision of the effect size estimate, the directness of the outcome and degree of publication bias (Brozek et al., 2009). GRADE was applied to both pooled estimates derived from meta-analysis, as well as individual study estimates where meta-analysis was not possible. Criteria for assessing outcome quality within the GRADE approach are outlined in Appendix D.

In reviews examining causal hypotheses (i.e., the effect of treatments) the GRADE approach rightly requires raters to automatically rate evidence from randomised controlled trials as high initially, and correlational (observational) studies as low initially. However GRADE has been adapted to examine the strength of evidence for other questions (Williams et al, 2010; Dudley et al., 2015). As noted elsewhere (Dudley et al., 2015), it would not be logical to apply such automatic downgrading to a review, such as ours, which seeks to examine the strength of evidence for and against a correlational hypothesis since this, by definition, depends on correlational studies. As such, outcome quality was initially rated as high, prior to downgrading based on GRADE criteria.

Analysis

Meta-analysis was conducted when at least three studies reported usable data on the relationship between a particular variable and treatment decision-making capacity. Meta-analyses were conducted using MetaXL software (EpiGear International, 2010 – 2015). Correlations were transformed into Fisher's Z, and a random effects model using the DerSimonian and Laird method was used to compute an overall effect size, together with 95% confidence intervals. This approach allows for true heterogeneity in effect size magnitude (due to differences in measurement, sample, etc.) to be distinguished from sampling error (Borenstein et al., 2009). Fisher's Z estimates were then back-transformed to Pearson's r to allow interpretation according to Cohen's (1988) conventions (0.1 = small; 0.3 = moderate; 0.5 = large).

The data presented in some studies did not follow a normal distribution, as indicated by the use of non-parametric statistics. Due to the small number of studies identified for each variable it was decided to pool the parametric and non-parametric data in the meta-analysis. Although we can assume that the underlying assumption of normality has been violated, the random effects model is adequate for estimating effect size - although the predictive power of the model is less (Karabatos, Talbott, & Walker, 2014).

Results

Study selection

The process of study selection is represented in the PRISMA diagram below (Fig. 1). Of the 2,057 papers initially identified, 1,993 were excluded after inspection of title or abstract. Full-text publications were sought for the remaining 64 papers. Of these, 40 were excluded; 16 did not include a measure of capacity, 11 were case

descriptions or editorials, 4 examined a different population, 6 did not measure capacity as an outcome variable, 2 examined research decision making capacity and 1 was a duplicate study. A full list of excluded studies with reason for exclusion is contained in Appendix E.

A total of 24 studies were included for review. Study characteristics are provided in Table 2. The included studies provided data on the relationship between TDMC and symptoms (k=12), insight (k=4), affect (k=3), cognitive performance (k=6), executive functioning, (k=2), duration of illness (k=2), education (k=5), metacognition (k=1) and various interventions (k=10).

Risk of bias

AHRQ ratings of observational studies and uncontrolled or non-randomised intervention studies are provided in Tables 3 and 4 respectively. Table 5 provides the Cochrane Risk of Bias ratings for randomised controlled trials.

Figure 1. PRISMA flow chart of study selection

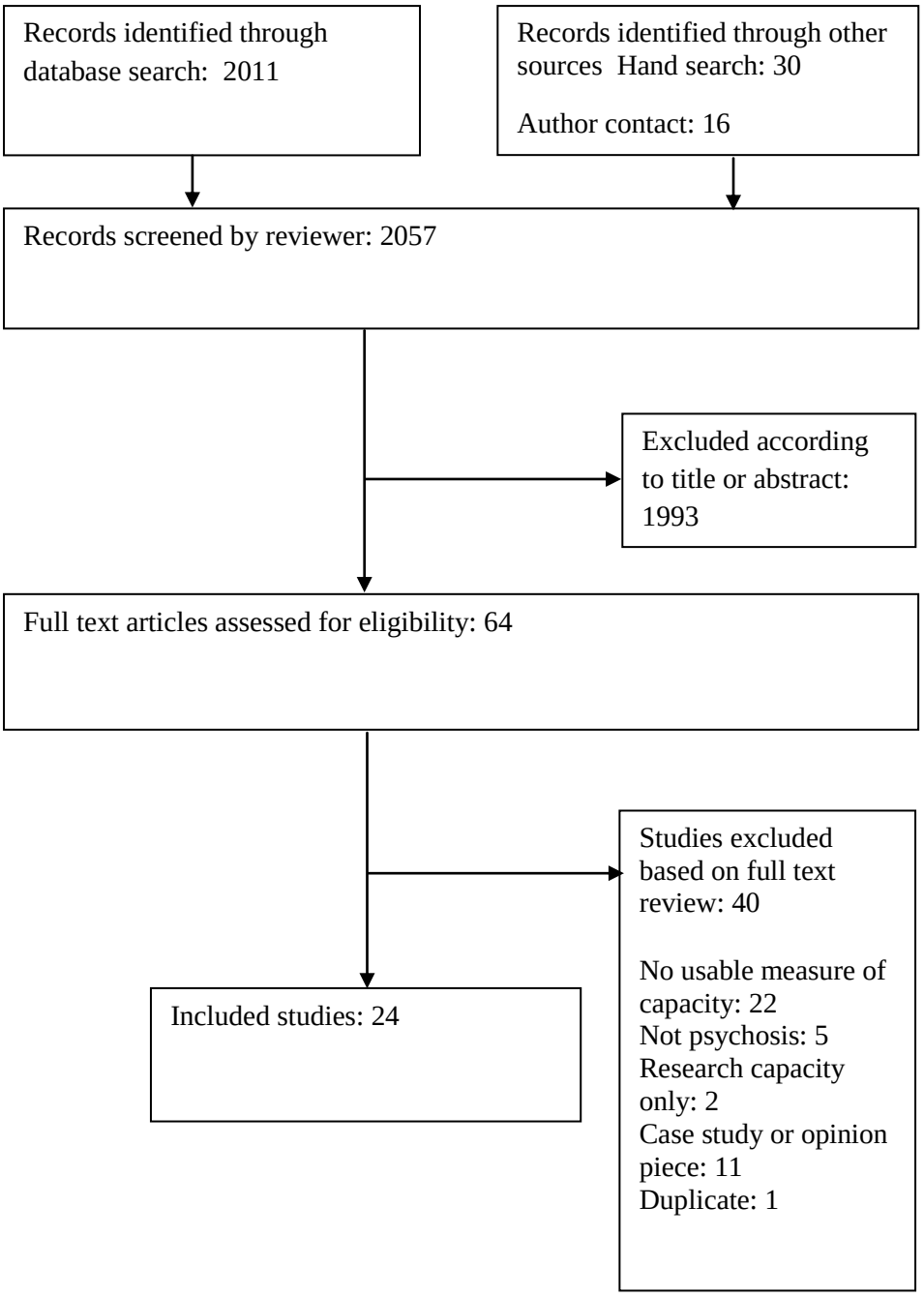


Table 2. Characteristics of included studies

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Cairns et al. (2005) England	Observational	General adult psychiatric ward	112 (63.4% Male; Depression 22.3%; Psychosis 55.4%; BPAD 18.8%; Other 3.6%) Mean age: 37.2 (11.8)	Diagnoses made by treating clinical team using ICD-10 criteria (WHO, 1993)	MacCAT-T	Brief Psychiatric Rating Scale (BPRS) Expanded Schedule for the Assessment of Insight (SAI-E) Mini Mental State Examination (MMSE) Brief Perceived Coercion Scale (BPCS)
Capdevielle et al. (2009) France	Observational	Adult psychiatry outpatients	60 (72% Male; Schizophrenia 100%) Mean age: 36.3 (10.9)	Diagnoses established by using the Patient Edition of the Structured Clinical Interview for DSM-IV (First et al., 1997). Consensus sought between treating psychiatrist and senior psychiatrist on research team.	Mac-CAT-T	Scale to Assess Unawareness of Mental Disoder (SUMD) Beck Depression Inventory – 2nd Ed. (BDI-II) Spielberger State Trait Anxiety Inventory (STAI) PANSS

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Di & Cheng (2013) China	Observational	Adult psychiatric inpatients from two hospitals	192 (81.2% Male; Diagnosis: Schizophrenia 100%) Mean age: 30.14)	Diagnoses made by clinical team using DSM-IV (APA, 1994)	Semi-structured Inventory for Competence Assessment (SSICA)	Brief Psychiatric Rating Scale (BPRS)
Dornan et al. (2015) Ireland	Cohort	Secure forensic hospital	37 (91.8% Male: Diagnosis: Schizophrenia 83.8%; Schizoaffective disorder 5.4%; BPAD 5.4%; Depression with pscyhotic features 2.7%; Psychotic disorder due to use of psychoactive substances 2.7%) Mean age: 32.3	Diagnoses made by clinical team using ICD-10 criteria (WHO, 1993) and DSM-IV TR criteria (APA, 2000)	MacCAT-T	Positive and Negative Symptom Scale (PANSS) Global Assessment of Functioning (GAF)
Elbogen et al. (2007) USA	RCT	Two community mental health programmes	469 (40% Male; Diagnosis; Schizophrenia: 59%; BPAD: 27%; Depression with psychotic features: 14%) Mean age: 42 (10.7)	Chart diagnosis of participants. Classification system not reported.	Decisional Competence Assessment Tool for Psychiatric Advance Directives (DCAT-PAD)	Brief Psychiatric Rating Scale (BPRS) Global Assessment of Functioning (GAF) Insight and Treatment Attitudes Questionnaire (ITAQ) American National Reading Test (AMNART) Similarities subscale from the Wechsler Adult Intelligence Scale – Third Edition (WAIS-III) Controlled Oral Word Association Test (COWAT) Hopkins Verbal Learning Test (HVLT)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Grisso & Appelbaum (1991) USA	Observational	Adult acute psychiatric ward	26 (Male 69%; Diagnosis: Schizophrenia and Schizoaffective disorder) Mean age: 36.8	Chart diagnosis of participants. Classification system not reported.	Measuring Understanding of Disclosure (MUD)	Brief Psychiatric Rating Scale (BPRS) Beck Depression Inventory (BDI) Vocabulary, Similarities, and Digit Span subtests of the Wechsler Adult Intelligence Scale-Revised (WAIS-R)
Grisso & Appelbaum (1995) USA	Observational	Adult acute psychiatric ward	75 (Male: 52%; Diagnosis: Schizophrenia or Schizoaffective disorder) Mean age: 34.5 (7.4)	Chart diagnosis of participants. Classification system not reported.	Understanding Treatment Disclosure (UTD) Perceptions of Disorder (POD) Thinking Rationally about Treatment (TRAT)	Brief Psychiatric Rating Scale (BPRS) Beck Depression Inventory (BDI) Vocabulary, Similarities, and Digit Span subscales from Wechsler Adult Intelligence Scale –Revised (WAIS-R)
Grisso, Appelbaum, & Hill-Fotouhi (1997) USA	Observational	Two adult psychiatric inpatient units	40 (80% Male; Diagnosis: Paranoid Schizophrenia 40%; Schizophrenia 30%; Schizoaffective disorder; 28%; Disorganized Schizophrenia 2%) Mean age: 39	Chart diagnosis of participants, confirmed using the Diagnostic Interview Schedule Screening Instrument (DISSI)	MacCAT-T	Brief Psychiatric Rating Scale (BPRS)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Hamann et al. (2011) Germany	RCT	University psychiatric hospital	61 (Male 38%; Diagnosis: Schizophrenia and schizoaffective disorder) Mean age: 40.7 (11.7)	Chart diagnosis of participants according to ICD-10 criteria (WHO, 1993)	Psychiatrist ratings of capacity	
Howe et al. (2005) Australia	Observational	Two public treatment facilities	110 (Male; 49.1%; Diagnosis: Schizophrenia 58.2%; Schizoaffective disorder 22.7%; BPAD 19.1%) Mean age: 37.2 (12.3)	Diagnoses made by treating clinical team, using DSM-IV criteria (APA, 1994). Confirmed by case review using a modified version of the Structured Clinical Interview for DSM-IV (Research Version) (SCID)	MacCAT-T	Positive and Negative Syndrome Scale (PANSS)
Kennedy et al. (2009) Ireland	Cohort	Secure forensic hospital	88 (Male: 90.9%: Diagnosis; Schizophrenia 69.3%; Depression with psychotic features 17.0%; Psychotic disorder due to substance misuse 5.7%; Schizoaffective disorder 4.5%; BPAD 3.4%) Mean age:	Diagnoses made by treating clinical team using ICD-10 criteria (WHO, 1993) and DSM-IV TR criteria (APA, 2000)	MacCAT-T	

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Koren et al. (2005) Israel	Observational	Mental health centre	21 (Male 61.9%: Diagnosis: Schizophrenia or schizophreniform disorder) Mean age: 23.9 (4.5)	Diagnosis made using Structured Clinical Interview for DSM-IV (SCID) (First et al., 1997), a systematic review of the medical record of participants and clinician information.	MacCAT-T	Wisconsin Card Sorting Test (WCST) Rating of confidence in answer (0-100) Accuracy score Free choice improvement Monitoring resolution Control sensitivity Monetary gains Similarities and Block design subscales from Wechsler Adult Intelligence Scale-Revised
Kleinman et al. (1996) Canada	RCT	University based general hospital and psychiatric hospital	26 (Diagnosis Schizophrenia)	Chart diagnosis using DSM-III criteria (APA, 1980)	Multiple choice questionnaire assessing knowledge of medication	
Mandarelli et al. (2012) France	Observational	Psychiatric intensive care unit	45 (Male: 44.4%: Diagnosis Schizophrenia / Schizoaffective Disorder 55.6%, Mood disorders 37.8%; Other 6.7%) Mean age: 41 (13.1)	Diagnoses made by treating senior psychiatrist using DSM-IV TR criteria (APA, 2000). Diagnoses agreed at MDT meetings, and confirmed by use of standardised clinical rating scales.	MacCAT-T	Brief Psychiatric Rating Scale (BPRS) Wisconsin Card Sorting Test (WCST) Mini Mental State Examination (MMSE)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Munetz & Roth (1985) USA	Quasi-experimental	Cognitive disorders clinic	25 (Male: 44%: Diagnosis: Schizophrenia 88%; Other 12%) Mean age: 48.6	Chart diagnosis of participants. Classification system not reported.	Questionnaire scores	
Naughton et al. (2012) Ireland	Quasi-experimental	Secure forensic hospital	19 (Male: 100%: Diagnosis: Schizophrenia 78.9%; Schizoaffective disorder 15.8%; Major depression with psychotic features 5.3%) Mean age: 36.7 (10.59)	Diagnoses made by treating clinical team using DSM-IV TR criteria (APA, 2000)	MacCAT-T	
Owen et al. (2011) UK	Cohort	Three general adult psychiatric wards	40 (Diagnosis: Schizophrenia or schizoaffective disorder)	Diagnoses made by treating clinical team using ICD-10 criteria (WHO, 1993)	MacCAT-T	Expanded Schedule for the Assessment of Insight (SAI-E) Matrix Reasoning subtest from Wechsler Abbreviated Scale of Intelligence (WASI) Brief Psychiatric Rating Scale (BPRS)
Owen et al. (2009) UK	Cross-sectional	Three general adult psychiatric wards	40 (Diagnosis: Schizophrenia and Schizoaffective disorder)	Diagnoses made by treating clinical team using ICD-10 criteria (WHO, 1993)	MacCAT-T	Expanded Schedule for the Assessment of Insight (SAI-E) Matrix Reasoning subtest from Wechsler Abbreviated Scale of Intelligence (WASI) Brief Psychiatric Rating Scale (BPRS)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Palmer et al. (2002) USA	Quasi-experimental	Psychiatry outpatient clinic	16 (Male: 56.2%: Diagnosis: Schizophrenia 68.8%; Schizoaffective disorder 18.8%; BPAD 6.3%; Psychosis not otherwise specified 6.3%) Mean age: 54.6 (7.2)	Chart diagnosis of participants using DSM-IV criteria (APA, 1994)	MacCAT-T Hopkins Competency Assessment Test (HCAT)	Positive and Negative Syndrome Scale (PANSS) Brief Psychiatric Rating Scale (BPRS) Mattis Dementia Rating Scale (DRS)
Raffard et al. (2013) France	Observational	Outpatients at University Department of Adult Psychiatry	60 (Male: 68.3%; Diagnosis: Schizophrenia 100% Mean age: 36.82 (11.14)	Diagnoses were established using the Patient Edition of the Structured Clinical Interview for DSM-IV procedures (First et al., 1997) by two independent psychiatrists.	MacCAT-T	Beck Cognitive Insight Scale (BCIS) Beck Depression Inventory (BDI-II) Spielberger State Trait Anxiety Positive and Negative Syndrome Scale (PANSS)
Rutledge et al. (2008) Ireland	Observational	Secure forensic hospital	102 (Male: 91.2%; Diagnosis Schizophrenia 81.4%; Schizoaffective disorder 6.9%; BPAD 7.2%; Psychotic Depression 7.2%) Mean age: 38.1	Diagnoses made by treating clinical team using ICD-10 criteria (WHO, 1993)	MacCAT-T	Positive and Negative Symdrome Scale (PANSS) Global Assessment of Functioning (GAF)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Schacter et al. (1994) Canada	Observational	Psychiatry outpatients	59 (Male: 83%: Diagnosis: Schizophrenia 100%) Mean age: 37	Diagnoses made by treating clinical team using DSM-III-R criteria (APA, 1987). 42 out of 59 participants subsequently administered the Structured Clinical Interview for DSM-III-R (Spitzer et al., 1987)	Information form and questionnaire	Brief Psychiatric Rating Scale (BPRS)
Wong et al. (2000) UK	Cohort	Local clinical services and GP	19 (Male: 76%: Diagnosis Schizophrenia 90.5%; Schizoaffective disorder: 9.5%) Mean age: 40.1 (10.6)	Chart diagnosis of participants using ICD-1o criteria (WHO, 1993)	Semi-structured interview	Brief Psychiatric Rating Scale (BPRS)

Authors, year, country	Design	Sample source	Participants (N, characteristics)	Diagnostic system used	Measure of capacity used	Outcome measures used
Wong et al. (2005) Hong Kong	Observational	Psychiatric hospital	81 (Male: 54.3%: Diagnosis: Schizophrenia 100%) Mean age: 36.9 (10.4)	Chart diagnosis of participants using DSM-IV criteria (APA, 1994)	MacCAT-T	Positive and Negative Syndrome Scale (PANSS) Montgomery and Asberg Depression Rating Scale (MADRS) Drug Attitude Inventory (DAI) Wechsler Adult Intelligence Test-Revised-Hong Kong version (WAIS-R-HK) Wisconsin Card Sorting Test (WCST) Wechsler Memory Scale (WMS) Monotone Counting Test

Table 3. Risk of bias assessment in cross-sectional observational studies.

Study ref	Unbiased selection of cohort?	Selection minimises baseline differences in prognostic factors?[1]	Sample size calculation?	Adequate description of the cohort?	Validated method for assessing TDMC?	Validated methods for ascertaining correlates?	Outcome assessments blind to clinical status?	Analysis controls for confounding?	Analytic methods appropriate?
Cairns et al. (2005)	Yes	Yes	No	Yes	Yes	Yes	Can't tell	No	Yes
Capdevielle et al (2009)	Yes	Yes	Partial	Yes	Yes	Yes	Yes	No	Yes
Di & Cheng (2013)	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
Grisso & Appelbaum (1991)	No	No	No	Yes	Yes	Yes	Can't tell	No	Yes
Grisso & Appelbaum (1995)	No	Yes	Partial	Yes	Yes	Yes	No	No	Yes
Grisso, Appelbaum, & Hill-Fotouhi (1997)	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
Howe et al (2005)	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes

Study ref	Unbiased selection of cohort?	Selection minimises baseline differences in prognostic factors?[1]	Sample size calculation?	Adequate description of the cohort?	Validated method for assessing TDMC?	Validated methods for ascertaining correlates?	Outcome assessments blind to clinical status?	Analysis controls for confounding?	Analytic methods appropriate?
Koren et al (2005)	Yes	Yes	No	Yes	Yes	Partial	Yes	No	Yes
Mandarelli et al (2012)	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Owen et al (2009)	Yes	Yes	Partial	Yes	Yes	Yes	No	Yes	Yes
Raffard et al (2013)	Yes	Yes	No	Yes	Yes	Yes	Partial	Yes	Yes
Rutledge et al (2008)	No	No	Partial	Yes	Yes	Yes	No	No	Yes
Schachter et al (1996)	No	Yes	No	Yes	No	Yes	Yes	Yes	Yes
Wong et al (2005)	No	Yes	No	Yes	No	Yes	No	No	Yes

Table 4. Risk of bias assessment for non-randomised or uncontrolled intervention studies.

Study ref	Unbiased selection of cohort?	Selection minimises baseline differences in prognostic factors?[1]	Sample size calculation?	Adequate description of the cohort?	Adherence to intervention?	Valid measure of TDMC?	Blind outcome assessment?	Adequate follow-up period?	Missing data at follow-up?	Analysis controls for confounding?	Analytic methods appropriate?
Dornan et al. (2015)	No	No	No	Yes	Partial	Yes	Partial	Can't tell	Yes	No	Yes
Kennedy et al. (2009)	No	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes
Kleinman et al (1996)	Yes	Yes	No	Yes	Yes	No	No	No	Yes	No	Yes
Munetz & Roth (1985)	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Naughton et al (2012)	No	No	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes
Owen et al (2011)	Yes	Yes	No	Yes	N/A	Yes	No	Yes	Yes	No	Yes
Palmer et al (2002)	No	No	No	Yes	Yes	Yes	Partial	Yes	No	No	Yes
Wong et al (2000)	No	No	No	Yes	Yes	Yes	Can't tell	Yes	Yes	No	Yes

Table 5. Risk of bias assessment for randomised controlled trials.

Study ref	Sequence generation	Allocation concealment	Blinding	Attrition	Selective reporting	Other
Elbogen et al (2007)	Yes	Yes	Unclear	No	No	Yes
Hamann et al (2011)	Yes	Yes	No	Yes	No	Yes

Overall GRADE ratings for each outcome are presented in the right hand column of Tables 6 and 7. The majority of the studies suffered from a risk of bias in relation to participant selection, with most studies using convenience samples. Those assessing capacity were often not blind to participants' outcomes on other variables included in the analysis. Funnel plots did not detect evidence of publication bias for the majority of the outcomes; however, there were generally too few studies to assess this (Ioannidis, 2005).

Outcomes

Symptoms (Figures 2-4)

Pooled data from 9 studies (N=610) suggested there was a moderate to large negative association between total psychotic symptom severity, as assessed by total Brief Psychiatric Rating Scale (BPRS; Overall & Gorham, 1962) or Positive and Negative Syndrome Scale (PANSS; Kay et al, 1987) scores, and the capacity of participants to understand information relevant to treatment decisions (r = -0.45, 95% CI -0.55, -0.34; I^2 60%; moderate quality evidence). All studies reported a negative correlation between symptom severity and understanding, although one study (Grisso et al. 1997) reported a considerably smaller effect size. Removing this led to a larger correlation and lower heterogeneity (r = -0.49, 95% CI -0.39, -0.56; I^2 46%). Data from 6 studies (N=453) suggested there was a small to moderate correlation between overall symptoms and the ability of participants to appreciate information relevant to a treatment decision (r = -0.23, 95% CI -0.14, - 0.32, I^2 0%; low quality evidence).

Table 6. Summary of meta-analytical estimates

Outcome and number of studies	Included studies	N	Pooled Fisher's Z (95% CI) Pooled r (95% CI)	Heterogeneity I^2 for Z	Quality (GRADE)
Relationship between total symptom severity and understanding (9 studies)	Capdevielle et al. (2009) Grisso & Appelbaum (1991) Grisso & Appelbaum (1995) Grisso & Appelbaum (1997) Howe et al. (2005) Raffard et al. (2013) Rutledge et al. (2008) Schacter et al. (1994) Wong et al. (2005)	610	Z= -0.49 (-0.62, -0.35) r = -0.45 (-0.55, -0.34)	60%	Moderate (-1 risk of bias)
Relationship between total symptom severity and appreciation (6 studies)	Capdevielle et al. (2009) Grisso & Appelbaum (1997) Howe et al. (2005) Raffard et al. (2013) Rutledge et al. (2008) Wong et al. (2005)	453	Z = -0.24 (-0.33, -0.14) r = -0.23 (-0.14, - 0.33)	0%	Low (-2 risk of bias)

Outcome and number of studies	Included studies	N	Pooled Fisher's Z (95% CI) Pooled r (95% CI)	Heterogeneity I^2 for Z	Quality (GRADE)
Relationship between total symptom severity and reasoning (7 studies)	Capdevielle et al. (2009) Grisso & Appelbaum (1995) Grisso & Appelbaum (1997) Howe et al. (2005) Raffard et al. (2013) Rutledge et al. (2008) Wong et al. (2005)	528	Z = -0.32 (-0.52, - 0.12) r = -0.31 (-0.48, - 0.12)	80%	Very Low (-2 risk of bias, -1 inconsistency)
Relationship between depression and understanding (3 studies)	Capdevielle et al. (2009) Grisso & Appelbaum (1991) Raffard et al. (2013)	146	Z = -0.04 (-0.21, 0.13) r = -0.04 (-0.20, 0.13)	0%	Moderate (-1 imprecision)
Relationship between verbal IQ and understanding (4 studies)	Grisso & Appelbaum (1991) Grisso & Appelbaum (1995) Koren et al. (2005) Wong et al. (2005)	203	Z = 0.45 (0.20, 0.69) r = 0.42 (0.20, 0.60)	60%	Low (-1 risk of bias, -1 indirectness)
Relationship between verbal IQ and reasoning (3 studies)	Grisso & Appelbaum (1995) Koren et al. (2005) Wong et al. (2005)	177	Z = 0.42 (0.27, 0.57) r = 0.39 (0.26, 0.51)	0%	Low (-2 risk of bias)
Relationship between years of education and understanding (3 studies)	Capdevielle et al. (2009) Raffard et al. (2013) Wong et al. (2005)	201	Z = 0.49 (0.35, 0.63) r = 0.46 (0.34, 0.56)	0%	Moderate (-1 risk of bias)

Outcome and number of studies	Included studies	N	Pooled Fisher's Z (95% CI) Pooled r (95% CI)	Heterogeneity I^2 for Z	Quality (GRADE)
Relationship between years of education and reasoning (3 studies)	Capdevielle et al. (2009) Raffard et al. (2013) Wong et al. (2005)	201	Z = 0.26 (0.12, 0.40) r = 0.26 (0.12, 0.38)	0%	Moderate (-1 risk of bias)

Figure 2. Forest plot of Fisher's Z effect sizes for total symptoms and understanding

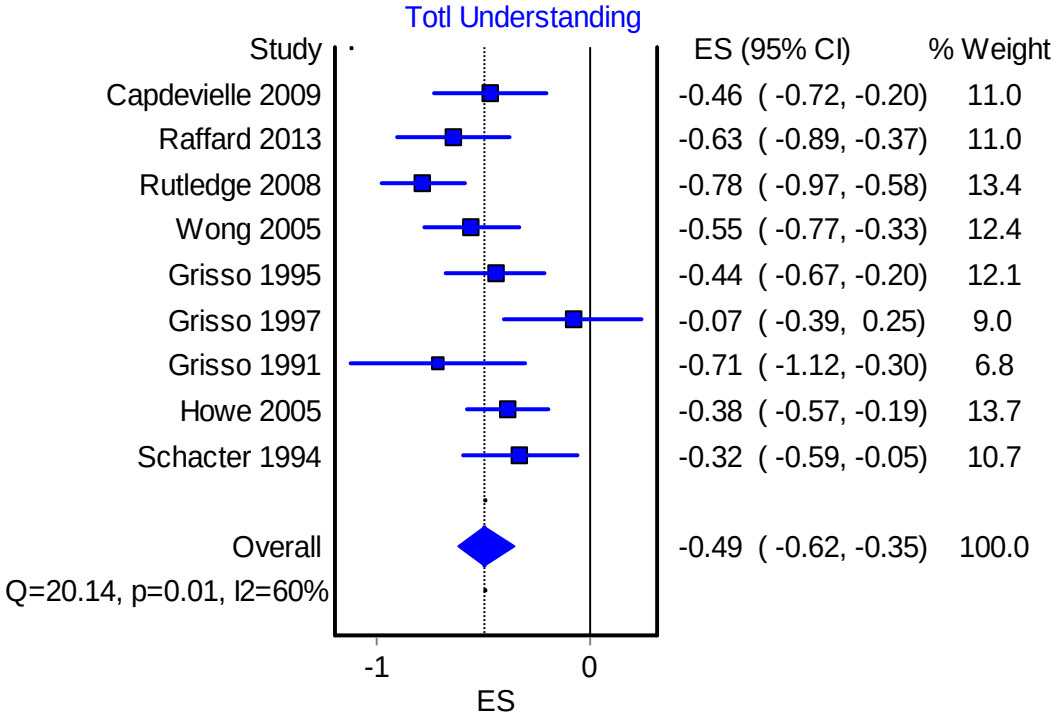


Figure 3. Forest plot of Fisher's z effect sizes for total symptoms and appreciation

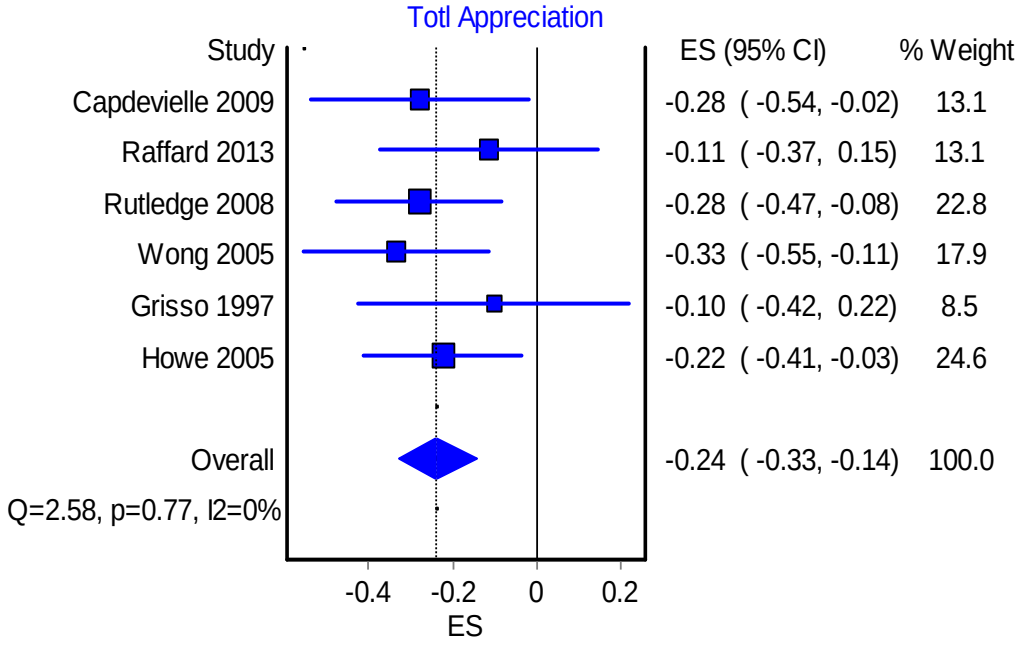


Figure 4. Forest plot of Fisher's z effect sizes for total symptoms and reasoning

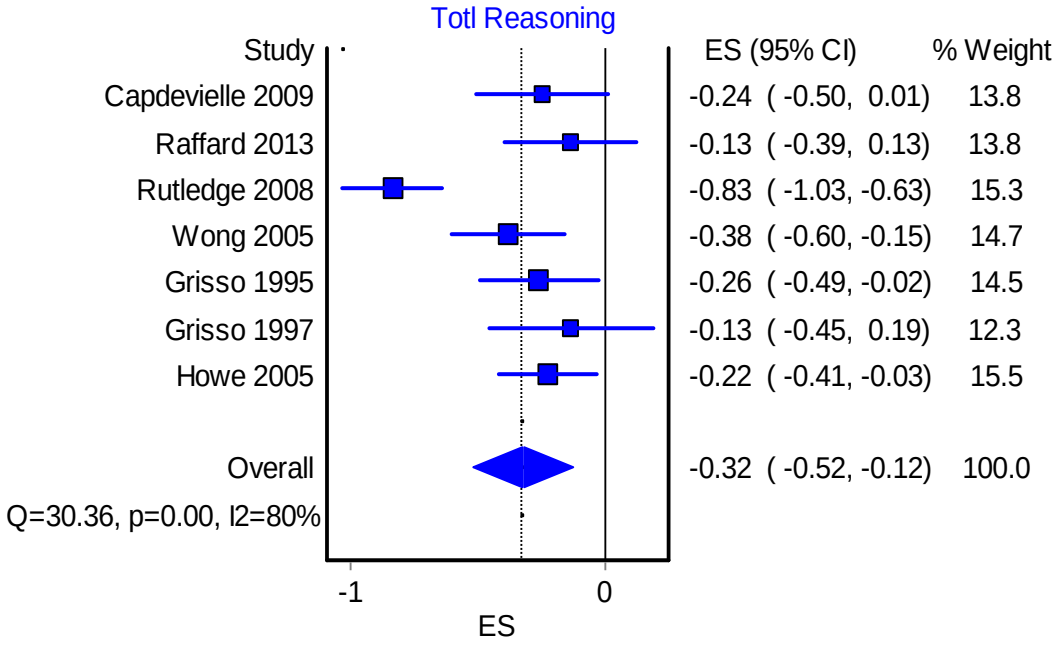
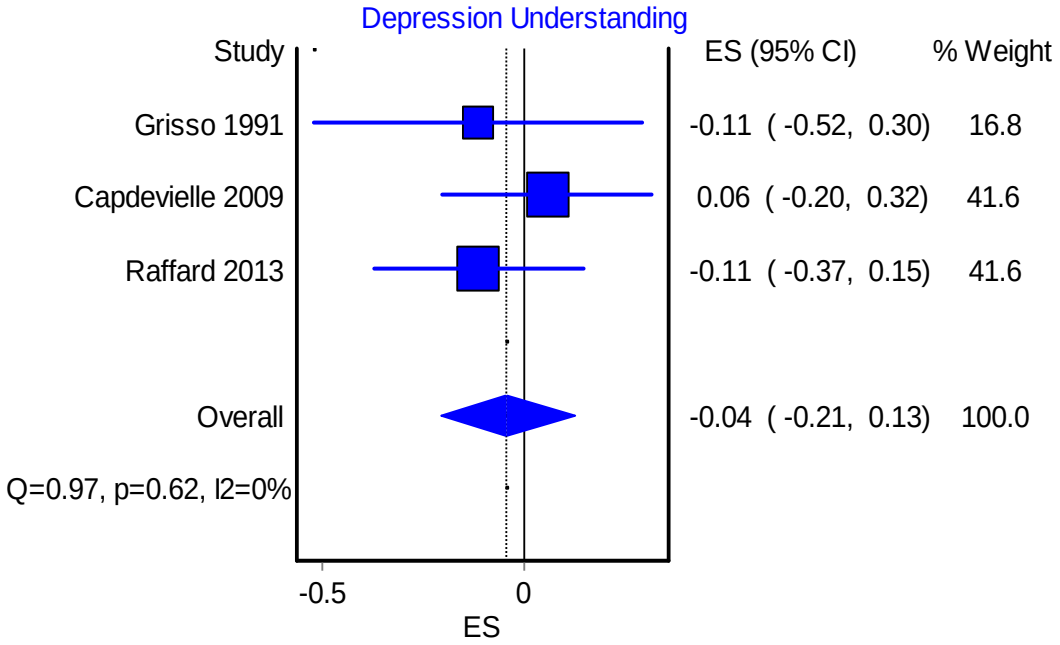


Figure 5. Forest plot of Fisher's z effect sizes for depression and understanding



According to data from 7 studies (N=528) there was a moderate correlation between total symptoms and the ability of participants to reason in relation to treatment decision-making (r = -0.31, 95% CI -0.48, - 0.12, I^2 80%; very low quality evidence). There was a high degree of heterogeneity in the results, which appeared to be attributable to the very large correlation reported by Rutledge et al. (2008), a study of forensic inpatients. Removing this study removed the heterogeneity and also lowered the effect size (r = -0.24, 95% CI -0.33, -0.14, I^2 0%).

Depression (Fig.5)

There was no evidence that depression was associated with the ability of participants to *understand* information about their treatment, although the estimate was low in quality due to imprecision and risk of bias (k=3, N=146, r=-0.04, 95% CI -0.20, 0.13, I^2 0%; moderate quality evidence).

Cognitive and intellectual performance (Figures 6 &7)

Moderate to large associations were observed between verbal cognitive functioning (assessed using subtests from the WAIS) and the ability of participants to understand information relating to treatment decision-making (k=4, N=203, r = 0.42, 95% CI 0.20, 0.60; I^2 60%; moderate quality evidence), and use reasoning (k=3, N=177, r=0.39, 95% CI 0.26, 0.51; I^2 0%; low quality evidence).

Figure 6. Forest plot of Fisher's z effect sizes for verbal IQ and understanding

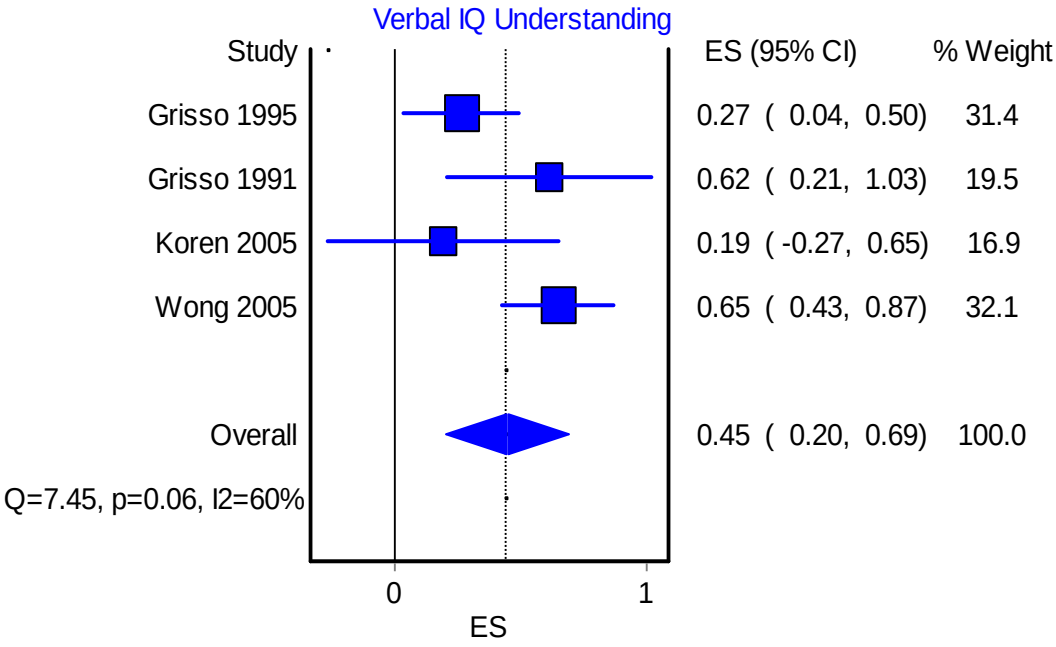


Figure 7. Forest plot of Fisher's z effect sizes for verbal IQ and reasoning.

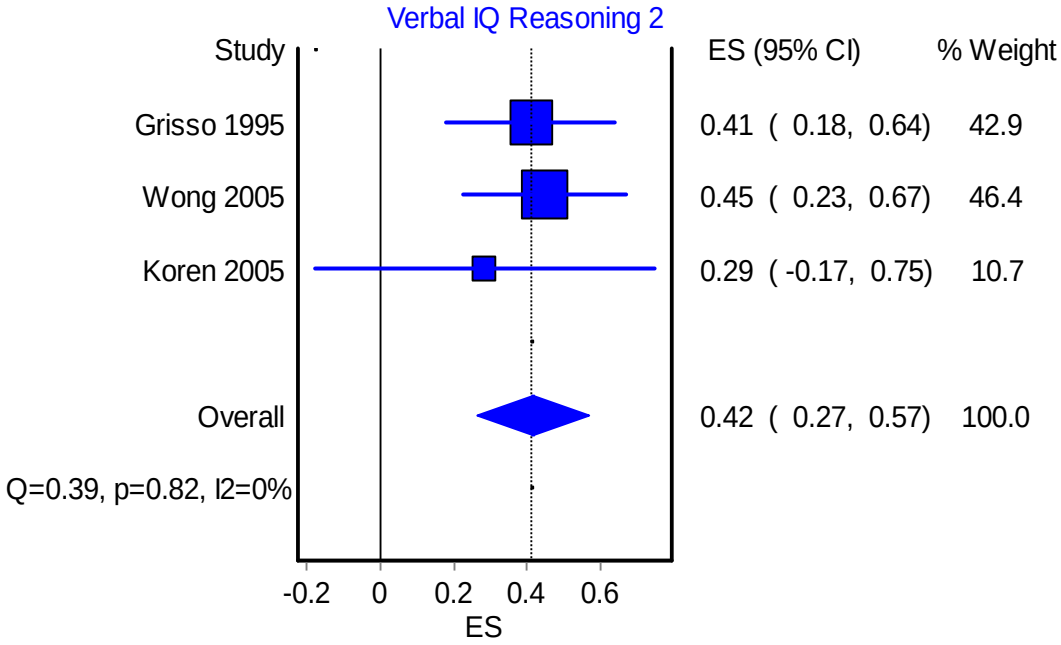


Figure 8. Forest plot of Fisher's z effect sizes for years of education and understanding

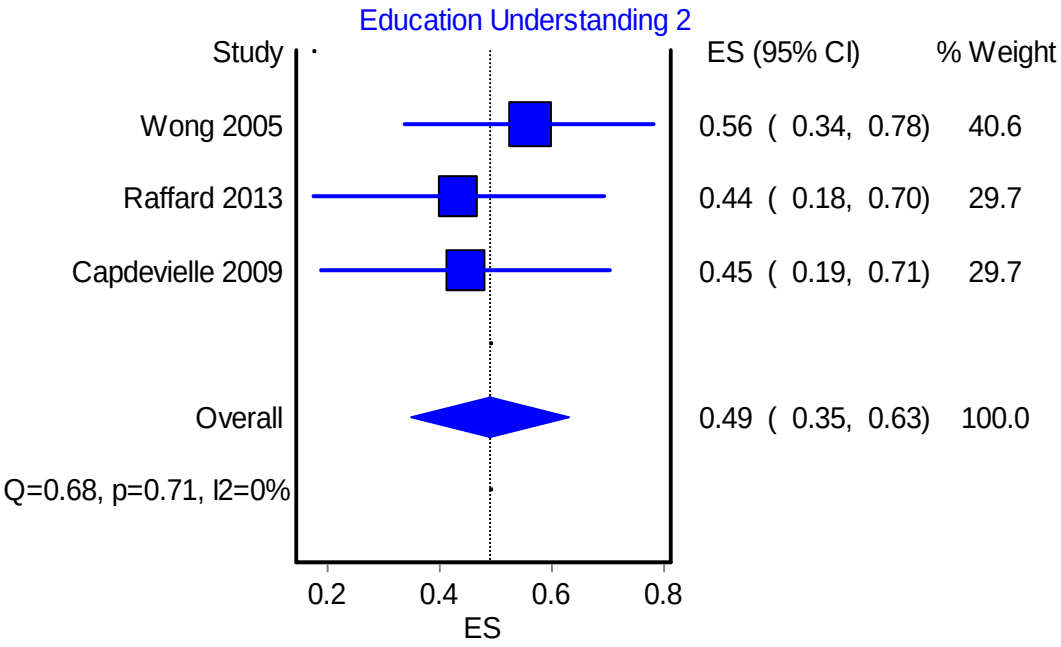


Figure 9: Forest plot of Fisher's z effect sizes for years of education and reasoning

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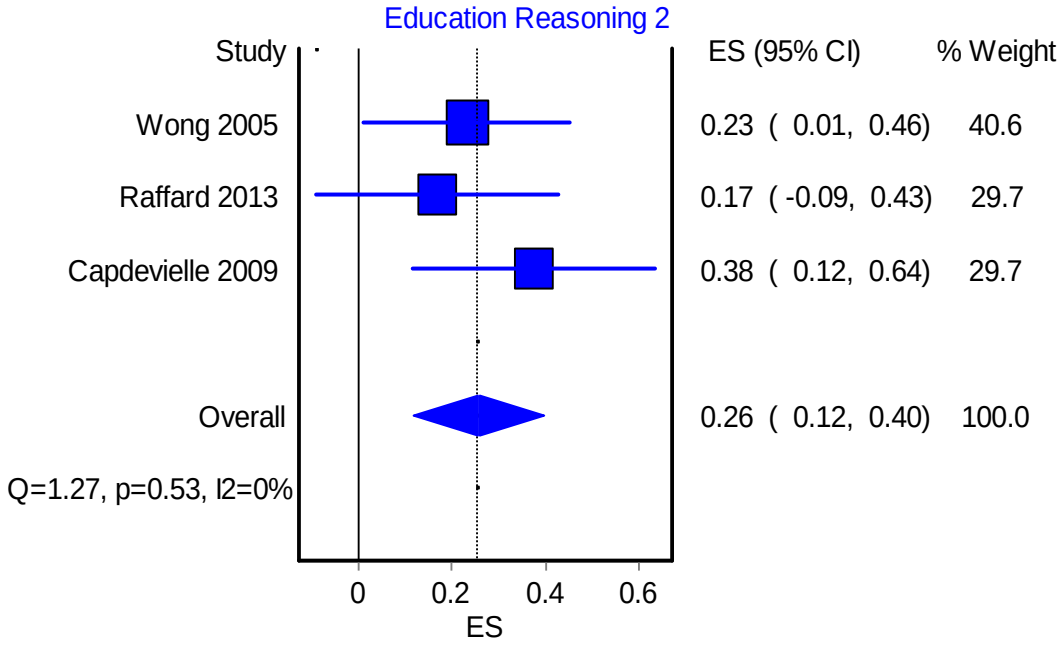

Years of education (Figures 8 & 9)

High quality evidence suggested a large association between years spent in education and the ability of participants to understand information relating to treatment decisions (k=3, N=201, r=0.46, 95% CI 0.36, 0.56; I^2 0%). The association between years of education and participants' reasoning ability was small to moderate in magnitude (k=3, N=201, r=0.26, 95% CI 0.12, 0.38; I^2 0%; moderate quality evidence).

Executive functioning

In a small study, Koren et al (2005) did not find clear evidence that executive functioning was associated with TDMC. The correlations that were observed were non-significant and small to moderate in magnitude; understanding (r = -0.35, 95% CI -0.68, 0.10 for trials to first category), appreciation (r = 0.41, (95% CI -0.03, 0.72 for numbers of categories), and reasoning (r = 0.31, 95% CI -0.14, 0.65 for number of categories). Mandarelli et al (2012) found that poor executive functioning was associated with lower ratings on all MacCAT-T domains, understanding (Cohen's d = 1.07, 95% CI 0.44, 1.71), appreciation (Cohen's d = 1.07, 95% CI 0.44, 1.71), and reasoning (Cohen's d = 0.32, 95% CI-0.28, 0.92). The inconsistent and imprecise findings meant the overall quality of evidence was rated as low.

Insight

Four studies examined the relationship between insight and treatment decision making capacity. Each assessed different aspects of insight, so were not conceptually similar enough to combine in meta-analysis. Capdevielle et al (2009) used the Scale to Assess Unawareness of Mental Disorder (SUMD) and found negative correlations between the five subscales and all domains of the MacCAT-T. For the mental

disorder subscale, there was a significant negative correlation with understanding (r = -0.34, 95% CI -0.55, -0.09) appreciation (r = -0.75, 95% CI -0.84, -0.61), reasoning (r = -0.74, 95% CI -0.84, -0.60), and expressing a choice (r = -0.41, 95% CI -0.60, -0.17). For the medication subscale there was a significant negative correlation with understanding (r = -0.38, 95% CI -0.58, -0.14), appreciation (r = -0.80, 95% CI -0.88, -0.69), reasoning (r = -0.72, (-0.82, -0.57) and expressing a choice (r = -0.35, 95% CI -0.55, -0.11). For the consequences subscale there was a significant negative correlation with understanding (r = -0.34, 95% CI -0.55, -0.09), appreciation (r = -.74, 95% CI -0.84, -0.60), reasoning (r = -0.69, 95% CI -0.80, -0.53), and expressing a choice (r = -0.44, 95% CI -0.62, -0.21). The awareness subscale was significantly negatively correlated with understanding (r = -0.32, 95% CI -0.53, -0.07), appreciation (r = -0.63, 95% CI -0.76, -0.45), reasoning (r = -0.61, 95% CI -0.75, -0.42) and expressing a choice (r = -0.34, 95% CI -0.55, -0.09). The attribution subscale was significantly negatively correlated with understanding (r = -0.39, 95% CI -0.59, -0.15), appreciation (r = -0.67, 95% CI -0.79, -0.50), reasoning (r = -0.63, 95% CI -0.76, -0.45) and expressing a choice (r = -0.38, 95% CI -0.58, -0.14). Raffard et al (2013) used the Beck Cognitive Insight Scale (BCIS) found that self-reflectiveness was significantly associated with reasoning ability (r = 0.43, 95% CI 0.20, 0.63). Owen et al (2009) used the Expanded Schedule for the Assessment of Insight (SAI-E) and found a very large significant difference in insight between those who were judged to have and not have intact TDMC (Hedge's g =-2.19 95% CI-1.83, -2.55). Finally, Elbogen et al (2007) used the Insight and Treatment Attitudes Questionnaire (ITAQ) and again found that insight was positively and significantly associated with reasoning *(*$\beta = 0.36$, $p < 0.05$). Although the evidence is consistent with the view that insight is associated with improved TDMC, in particular reasoning

ability, the quality of the evidence was judged to be low in quality overall because of risk of bias, and indirectness.

Table 7. Summary of individual observational study findings

Correlate (number of studies)	Studies included	N	Outcome measures used	Key findings	Quality (GRADE)
Executive functioning (2 studies)	Koren et al. (2005) Mandarelli et al. (2012)	66	Wisconsin Card Sorting Test (WCST)	Some evidence of large correlations in one study, but no clear evidence in other.	Low (-1 risk of bias, -1 inconsistency)
Insight (5 studies)	Cairns et al. (2005) Capdevielle et al. (2009) Owen et al. (2009) Raffard et al. (2013) Elbogen et al (2007)	813	Scale to Assess Unawareness of Mental Disorder (SUMD) Expanded Schedule for the Assessment of Insight (SAI-E) Beck Cognitive Insight Scale (BCIS) Insight and Treatment Attitudes Questionnaire (ITAQ)	Insight strongly and significantly associated with TDMC, and reasoning in particular	Low (-1 risk of bias, -1 indirectness)
Duration of illness (2 studies)	Raffard et al. (2013) Wong et al. (2005)	141	Years since diagnosis	No clear evidence of association with TDMC	Moderate (-1 risk of bias)
Metacognitive ability (1 study)	Koren et al. (2005)	21	Participant ratings of confidence in the correctness of the sort (0-100)	Some evidence that metacognitive ability is associated with TDMC	
Perceived coercion	Cairns et al. (2005)	112	Brief Perceived Coercion Scale (BPCS)	Participants judged to have impaired capacity were more likely to report high perceived coercion	
Anxiety	Capdevielle et al. (2009) Raffard et al. (2013)	120	Spielberger State- Trait Anxiety Inventory (STAI Trait and STAI State)	Both state and trait anxiety had a small to medium *positive* correlations with appreciation and reasoning, but not understanding or communicating.	Moderate (-1 imprecision)

Table 8. Summary of individual intervention study findings

Interventions	Studies included	N	Outcome measure used	Key findings	Quality (GRADE)
Altering presentation of material (5 studies)	Kennedy et al. (2009) Kleinman et al. (1996) Munetz & Roth (1985) Palmer et al. (2002) Wong et al. (2000)	176	Change in capacity scores	Repeating and simplifying information associated with improved capacity. Some evidence that extra information reduces capacity.	Low (-2 risk of bias)
Treatment as usual and medication (2 studies)	Dornan et al. (2015) Owen et al. (2011)	237	Change in capacity scores	Treatment as usual (including antipsychotics) associated with improved capacity	Low (-2 risk of bias)
Shared decision making (SDM) (2 studies)	Elbogen et al. (2007) Hamann et al. (2011)	442	Change in capacity scores	SDM caused improved capacity in one trial, but not another	Low (-1 risk of bias, -1 inconsistency)
Metacognitive training (1 study)	Naughton et al. (2012)	19	Change in capacity scores	MCT associated with improved capacity scores	

Duration of illness

Two studies provided moderate quality data on the relationship between duration of illness and TDMC (Raffard et al. 2013; Wong et al., 2005). Both reported non-significant small negative correlations between duration of illness and the understanding domain of the MacCAT-T (Raffard et al, 2013; r = -0.12, 95% CI -0.36, 0.14; Wong et al., 2005; $\rho = -0.23$, $p > 0.05$), and one reported non-significant small negative correlations between duration of illness and appreciation (r = -0.09, 95% CI -0.34, 0.17), reasoning (r = -0.19, 95% CI -0.42, 0.06) and expressing a choice (r = -0.18, 95% CI -0.42, 0.08) (Raffard et al., 2013).

Metacognitive ability

In one small study, Koren et al (2005) found that metacognitive ability was significantly associated with the ability of participants to understand information relating to treatment (r = 0.60, 95% CI 0.23, 0.82 for control sensitivity). Although not significant, correlations of similar magnitude were observed for appreciation (r = 0.40, 95% CI -0.04, 0.71 for monetary gains) and reasoning (r = 0.43, (95% CI -0.00, 0.73), although these were not statistically significant.

Perceived coercion

Cairns et al. (2005) found that participants judged to have impaired capacity were more likely to report higher levels of perceived coercion (Mann-Whitney U = 422.5, $p < 0.001$).

Anxiety

Two studies reported *positive* correlations between state and trait anxiety and aspects of TDMC – i.e., greater anxiety was linked to greater treatment decisional capacity.

State anxiety was significantly correlated with the appreciation domain in both studies (r=0.27, 95% CI 0.02, 0.49; Capdevielle et al., 2009; r=0.36, 95% CI 0.12, 0.56; Raffard et al., 2013), whereas trait anxiety was only significantly associated with appreciation in one (r=0.33, 95% CI 0.08, 0.54; Capdevielle et al., 2009; r=0.22, 95% CI -0.04, 0.45; Raffard et al., 2013). A similar pattern of findings was observed for the relation between state anxiety and reasoning (r=0.32, 95% CI 0.07, 0.53; Capdevielle et al., 2009; r=0.27, 95% CI 0.02, 0.49; Raffard et al., 2013) and trait anxiety and reasoning (r=0.38, 95% CI 0.14, 0.58; Capdevielle et al., 2009; r=0.15, 95% CI -0.11, 0.39; Raffard et al., 2013). In both studies, non-significant small correlations were reported for state and trait anxiety and understanding and expressing a choice.

Interventions

Of the 10 intervention studies we identified, 5 assessed the effect of altering the presentation of information on TDMC, 2 examined the effect of usual treatment, 2 examined the effect of shared decision making, and 1 study examined the effect of metacognitive training.

Altering presentation of material

Repetition of information, and discussion of presented information with others, were associated with increases in TDMC in three studies (Kleinman et al., 1996; Munetz & Roth, 1985; Palmer et al., 2002). The effect size for completing an educational review process in Kleinman et al. (1996) was moderate (Cohen's d = 0.27, 95% CI -0.51, 1.06), and for formal presentation in Munetz & Roth (1985) was large (Cohen's d = 1.83, 95% CI 0.48, 3.18). There was not enough data provided in Palmer et al. (2002) to calculate effect sizes, there was a statistically significant increase in scores

on the Hopkins Competency Assessment Test (χ^2 = 12.05, N=13, p=0.002). However, Kennedy et al (2009) found that providing extra information to participants in a forensic setting was associated with a fall in TDMC, with a statistically significant proportion of the sample becoming incapable of making a treatment choice following the presentation of extra information (Cohen's d = 0.75, 95% CI 0.30, 1.20). Wong et al (2000) successively simplified the presentation of information and found that as the task was simplified, TDMC improved significantly (Cochran's Q = 14.4, df = 3, p < 0.01). Overall, the evidence on the effect of changing presentation of information was judged to be of low quality.

Treatment as usual and medication

Owen et al (2011) found that 37% of patients regained TDMC following a month of treatment in hospital. Recovery of TDMC was strongly associated with improved insight in this study (OR = 13.28).

Dornan et al. (2015) found that patients receiving treatment as usual, which included 25 hours per week of individual programmed activities, as well as treatment with antipsychotic medications, improved on all domains of TDMC – understanding (Cohen's d = 0.62, 95% CI 0.15, 1.09), appreciation (Cohen's d = 0.39, 95% CI-0.07, 0.85), and reasoning (Cohen's d = 0.63, 95% CI 0.16, 1.09). Dornan et al (2015) also found that patients treated with clozapine had larger improvements in TDMC than patients treated with other antipsychotics. This effect was largest and significant in the appreciation domain (Cohen's d = 2.10, 95% CI 1.15, 3.05), and smaller and non-significant in the understanding (Cohen's d = 0.75, -0.09, 1.59) and reasoning domain (Cohen's d = 0.71, 95% CI -0.13, 1.55). The evidence here was judged be of

low quality, and indicate that antipsychotic medication is associated with improvements in TDMC in some but not all individuals.

Shared decision making

Two methodologically strong studies examined the effect of a shared decision making (SDM) intervention on TDMC. However, these studies found conflicting results. Elbogen et al (2007) found a significant effect of SDM on reasoning ($F(1,355) = 4.30$, $p < 0.05$), but not appreciation or understanding, whereas Hamann et al (2011) found a non-significant but negative effect on TDMC (Cohen's d = -0.34, 95% CI -0.85, 0.16). Elbogen et al (2007) reported a larger sample size than Hamann et al, and used a more established measure of treatment decision-making capacity. There was not enough information contained in the report of Elbogen et al. (2007) to calculate effect size.

Metacognitive training

Naughton et al (2012) found that patients who received group metacognitive (MCT) training had improved MacCAT-T scores. The effect sizes and confidence intervals were calculated and showed that MCT training had a significant effect on understanding (Cohen's d = 1.44, 95% CI 0.42, 2.45) and reasoning (Cohen's d = 1.21, 95% CI 0.22, 2.20), but a smaller non-significant effect on the appreciation domain (Cohen's d = 0.19, 95% CI -0.72, 1.10). A dose-response effect was reported, in that the more sessions attended, the greater the improvements in capacity. This early evidence from a small study (N=19) was rated as low in quality due to imprecision and lack of blind ratings.

Discussion

Summary of results

Our primary objective was to identify which clinical, demographic and intervention-related variables are associated with treatment decision-making capacity (TDMC) in psychosis, using meta-analysis where appropriate to estimate the significance and magnitude of any relationships. We identified 24 relevant studies, over half of which were published in the last 10 years. Overall, these reported data from 1,823 individuals with psychosis.

As might be expected, the variables studied most frequently were psychotic symptoms and cognitive ability. Good quality meta-analytical evidence confirmed that symptom severity was strongly associated with the ability of participants to understand treatment-relevant information, with smaller yet still significant associations with appreciation and reasoning. There was less evidence on the relationship between cognition and capacity, although moderate to large associations between verbal cognitive functioning and both reasoning and understanding emerged from the meta-analyses. There were similar findings for duration of education. Surprisingly, the relationship between capacity and emotion has not been studied in any great depth. However studies that do exist have found no evidence to suggest that depression is related to the ability to understand treatment-relevant information, and whether this is related to other components of TDMC remains unclear. Two studies reported some surprising evidence that greater anxiety may be related to *better* appreciation and reasoning, but more evidence is needed to support this link.

There was some evidence that aspects of executive functioning were related to TDMC, with emerging evidence that metacognitive awareness and insight (including

self-reflectivity) are associated with improved TDMC. Although we did not find clear evidence that duration of illness is linked to reduced TDMC, only two studies reported data on this outcome.

There was also emerging evidence to suggest that various interventions, ranging from the simple to the more complex, may be associated with changes in how people with psychosis understand, appreciate, and reason with information related to health care and treatment decisions. The presentation of information may be an important consideration in interventions to support decision-making, and there was some evidence that simply providing extra information may actually hinder treatment decisional capacity in this group. Randomised controlled trials will be required to test these emerging hypotheses. Indeed, the only randomised controlled trial to use an established measure of TDMC found that a shared decision-making (SDM) approach significantly enhanced the successful use of reasoning in relation to treatment decision-making. On the other hand, there was no effect of SDM on understanding or appreciation in this large trial (N=469; Elbogen et al 2007). Although another smaller trial (N=61; Hamann et al 2006) found no benefit of SDM on TDMC, the researchers measured this using a less validated 10-point scale, which was rated by participating clinicians rather than independent researchers.

Overall, this review has shown there is promising evidence that treatment decision-making capacity may be responsive to intervention. On the other hand, it has been 25 years since the first study of TDMC in psychosis, and we still lack robust evidence from randomised controlled trials to know how to support it.

Limitations

This review was broad in scope and to some extent exploratory, and we were limited by the studies that have been carried out. Nonetheless, we have provided a detailed snapshot of the available evidence on correlates and risk factors for impaired TDMC, and we have identified important gaps and weaknesses in the literature. The correlational nature of much of the data precludes causal interpretations and experimental studies conducted within a causal-interventionist framework (Kendler & Campbell, 2009) are required to develop and test a theoretical model of TDMC in psychosis. We have also only considered decision-making in relation to treatment decisions, which may confound the specific nature of the decision with the individual person's capacities. Although this means our results have high clinical utility, there is a wealth of data on cognitive and neuropsychological factors involved in decision-making ability in psychosis – for example, as measured by the Wisconsin Card Sorting Task (Wing et al., 2013). The development of a comprehensive theory of TDMC in psychosis will require integration and synthesis of this literature, but this was outwith the scope of the current review.

Only a small number of studies were included in most of the meta-analyses. This limits the ability of the meta-analysis to detect between-study variance (Borenstein et al., 2009), publication bias (Ioannidis & Trikalinos, 2007) and smaller yet theoretically important effects. Nonetheless, as Sheskin (2003) states *"one should view combined / pooled probability and effect size values computed in meta-analysis as rough estimates".*

We focused on correlational data in this review, but arguably it is of greater clinical relevance to consider what distinguishes those judged to have TDMC and those who

do not. Although dichotomising continuous data in this way greatly diminishes statistical power to detect differences (Altman & Royston, 2006), it could be argued that TDMC is not continuously distributed. As with the ongoing debate over the relative merits of categorical or dimensional approaches to psychopathology (Lawrie et al., 2016), we suggest both approaches are likely to be useful.

Some of the data used in the meta-analysis violated the assumption of normality, and we used an effect size converter to convert parametric and non-parametric correlations to Fisher's Z effect size. This violation does reduce predictive power, but is still suitable for estimation of effect size in meta-analysis (Karabatos, Talbott, & Walker, 2014).

Implications

Relatively little research has focused on psychological mechanisms that may contribute to decision-making capacity in people who have experienced psychosis. The reasons for this are unclear. Although capacity is a legal concept, psychologists have been closely involved in its development and application in psychosis (Grisso & Appelbaum, 1991). Whatever the reason, we encourage further research into the role of reasoning biases (Kahnemen, 2003), attitudes and beliefs (Armitage & Conner, 2001), emotions such as fear or anxiety (Rogers, 1975; Hartley & Phelps, 2012) values (Mukherjee & Kable, 2014) and the application of psychological models of healthcare decision-making. Such work will take us closer to developing an integrated model of TDMC in psychosis, and the development of effective psychological strategies to support it.

Although we found a large association between total symptom severity and TDMC, only two studies identified for this review (Dornan et al., 2015; Owen et al., 2011)

explicitly measured treatment decision making capacity before and after treatment with antipsychotic medications. Given the link between ability to make treatment decisions and perceived autonomy and recovery, investigating how current treatments and interventions for psychosis impact on TDMC may be an important outcome for service users. Without such research, the hypothesis that pharmacological and psychological approaches improve TDMC remains untested.

Most non-pharmacological intervention studies have focussed on altering the way information is presented as a means to increase TDMC. Further research should investigate more sophisticated interventions such as metacognitive training, and other psychological therapies. Improved decision-making ability is an outcome of interest to service users in a recovery-focused model of health care delivery – capacity and autonomy are closely linked and may be more important than reduction in symptoms for the person affected (Law et al., 2015).

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Chapter 2: Empirical Journal Article

The relationship between cognitive biases, treatment decision-making capacity and recovery in psychosis

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Abstract

Introduction: Cognitive biases and subjective recovery are a major focus of psychological approaches to psychosis, yet whether they are associated with domains of treatment decision making capacity (TDMC) is unknown. The current study tests the hypothesis that cognitive biases account for a significant amount of variance in TDMC after taking into account known predictors (symptoms, insight), and that higher TDMC is associated with greater subjective recovery.

Method: Twenty-five participants diagnosed with non-affective psychosis completed measures of TDMC, psychotic symptoms and cognitive biases; 17 also completed measures of cognitive insight and subjective recovery. Hierarchical multiple regressions and correlational analyses were used to test the main hypotheses.

Results: Cognitive biases, 'jumping to conclusions bias' in particular, predicted a moderate amount of variance in the TDMC domains of 'understanding' and 'reasoning', but did not add predictive power to a model containing symptoms, insight, and cognitive functioning. The appreciation domain was most strongly predicted by cognitive biases, insight, and cognitive functioning. The results suggest there may be more complex relationships between these variables. Post hoc analyses found that positive symptoms may mediate the relationship between cognitive biases and understanding; however there was no evidence that emotional distress mediated the effect of cognitive biases on TDMC. TDMC was not associated with subjective recovery in this sample.

Conclusions: Psychosis-specific cognitive biases may be involved in TDMC in this group, but further research is required to clarify the exact nature of this

relationship. Keywords: Psychosis; schizophrenia; treatment decision-making capacity; competence; cognitive biases; jumping to conclusions.

Introduction

The ability to make informed and reasoned decisions is referred to as 'having capacity' to make those decisions, and is an essential component of informed consent for physical and mental health care interventions. The most widely accepted conceptualisation of capacity involves four key domains identified by the MacArthur Treatment Competence Study (Appelbaum & Grisso, 1995): understanding, appreciation, reasoning, and expressing a choice. These four domains are also used in the legal definition of capacity described in the Adults with Incapacity (Scotland) Act (2000) which defines incapacity as being incapable of (a) acting; or (b) making decisions; or (c) communicating decisions; or (d) understanding decisions; or (e) retaining the memory of decisions.

These studies led to the development of the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), which has the most empirical validation of all research tools in decision making capacity (Dunn et al., 2006). The MacCAT-T was designed to reflect important legal principles, and since then a number of studies have used it to investigate the role of clinical variables on capacity, (Capdevielle et al., 2009; Dornan et al., 2015; Owen et al., 2011). This is important as decisions about capacity to consent to treatment are made by clinicians in the majority of instances, however there is little consensus on the clinical aspects of capacity. In addition, most research has focused on stable characteristics or symptoms, rather than psychological factors (Okai *et al*, 2007). This research has shown that decision making capacity is related to cognitive impairment (Carpenter *et al*., 2000; Palmer *et al*., 2004; Stroup *et al*., 2005), level of insight (Maxmin *et al*., 2009; Ruissen *et al*., 2012), diagnosis, particularly diagnosis of psychotic disorder (Okai *et al*, 2007) and manic episodes (Owen *et al*., 2009).

Studies have consistently shown that people who have a diagnosis of a psychotic disorder are more likely to be deemed incapable of making treatment decisions (Okai *et al*., 2007; Owen *et al*., 2009). This has led to emerging research on the specific aspects of psychotic experiences that influence such judgements. For example, it has been shown that the severity of general psychopathology in people with psychosis is inversely correlated with scores on measure of decision making capacity (Rutledge *et al.*, 2008). More specifically, research has focused on whether positive or negative symptoms explain more of the variance in decision making capacity, although the results of these studies have been inconsistent, with some reporting that positive symptoms such as hallucinations are more significantly related (Owen *et al.*, 2009, Rutledge, *et al*., 2008; Howe *et al*., 2005), and some other studies suggesting that negative symptoms and cognitive limitations have more of a role (Palmer & Salva, 2007).

The strong association between psychosis and decisional incapacity suggests the possibility that psychological factors involved in psychotic experiences may also negatively affect decision-making. Cognitive models of psychosis propose that specific cognitive biases contribute to the formation and maintenance of the positive symptoms of psychosis, such as delusions and hallucinations (Morrison, 2001; Garety et al., 2001; Freeman et al., 2002). There is a growing body of evidence showing that both cognitive and affective processes affect the development and maintenance of psychosis. A study by Freeman et al. in 2013 showed that current paranoid thinking was associated with anxiety, depression, greater anticipation of threat events, negative interpretations of ambiguous events, a self-focussed cognitive style, and negative ideas about the self. Attachment style (Berry, Barrowclough, &

Wearden, 2008), childhood adversity (Read et al., 2014), interpersonal schema (Birchwood et al., 2004), and metacognition (MacBeth et al., 2014; Lysaker et al., 2005) have all been found to have a role in psychosis. Cognitive reasoning biases have been the most well researched of these psychological factors, and the most empirically validated of these is the jumping to conclusions (JTC) bias. A review by Garety and Freeman (1999) found that of 14 studies reviewed, 11 provided evidence for reasoning biases in people with delusions. In a recent meta-analysis of 55 studies, a robust association between overall psychotic symptoms and the JTC bias was observed, although this was only weakly associated with delusion severity (Dudley, Taylor, Wickham & Hutton, 2015). Other cognitive biases such as heightened self certainty, reduced theory of mind, and poor source memory have been found to be related to schizotypy (Sacks, Weisman de Mamani, & Garcia, 2012), and current paranoid thinking has been found to be related to hypervigilance, negative interpretations of events, self-focused cognitive style, and negative ideas about the self (Freeman *et al*., 2012).

A variety of psychological therapies that focus on modifying cognitive biases in psychosis have been developed, including cognitive behavioural therapy (CBT). Although the promise of earlier forms of CBT have been challenged by meta-analyses suggesting small benefits at best, there have been a number of recent developments that give grounds for optimism. These include evidence that CBT is effective at preventing psychosis in those at risk of developing it (Hutton & Taylor, 2014), evidence that metacognitive training, an approach that targets cognitive biases specifically, appears to have a robust effect on positive symptoms (Moritz et al., 2014; Eichner & Berna, 2016) and more recent evidence suggests brief reasoning

interventions focused on modifying the JTC bias can effect significant changes in delusion severity (Garety et al., 2015; Waller et al., 2015). Overall, it appears that cognitive biases in psychosis are amenable to change, and that reducing these biases may be linked to improved symptoms.

The extent to which decisional capacity is amenable to psychological or pharmacological intervention remains unclear. Although a Delphi study carried out in 2010 by Morrison and Barratt, found that experts considered the statement "CBT should assist the maintenance of a client's capacity to make informed decisions about their lives" to be one of the essential elements of CBT for psychosis, no research has examined its effects on capacity. Palmer *et al*. (2013) found that decisional capacity in research participants showed a general pattern of stability, however in a clinical sample of in-patients Owen *et al*. (2011) found that 37% of patients who were admitted without decision making capacity had regained capacity one month later. All who had regained capacity had improved on symptom scores, but an improvement in symptoms was not sufficient to have regained capacity. A small study by Naughton *et al*. (2012) used group meta-cognitive therapy (MCT) as an intervention with forensic patients with a psychotic illness. Although symptoms did not improve in this group, there was a significant change in mental capacity as measured by the MacCAT-T. Two randomised controlled trials have been conducted to assess the impact of shared decision making on assessments of capacity (Elbogen et al., 2007; Hamann et al., 2011). These trials found conflicting results, while Elbogen et al. (2007) found that an SDM intervention improved participants' reasoning, while Hamann et al. (2011) found that an SDM intervention had no significant effect on overall capacity. In summary, there is suggestive evidence that

treatment decisional capacity in psychosis might respond to treatment, but there is a lack of definitive evidence from randomised controlled trials.

This lack of robust evidence is troubling, given the likely importance of capacity to people with psychosis and their clinicians. However whether capacity is associated with recovery as defined by users of mental health services is unclear. Although a recent Delphi study carried out with people who have experienced psychosis found that 86% endorsed the statement that "recovery is the process of regaining active control over one's life" and 80% believed that "when other people are making decisions about the other person's life" this is a factor that hinders recovery (Law & Morrison, 2014), to date no studies have examined whether there is a correlation between capacity and recovery in psychosis. Although it seems plausible that greater decisional capacity would be associated with greater subjective recovery from psychosis, it may also be the case the current concepts of capacity are, when applied by clinicians, underpinned by a model of psychosis (Shek et al., 2010) which some service users would not endorse (Pitt et al., 2007).

Overall the research outlined above shows that people who experience psychosis are more likely to be deemed not to have capacity, that there remains unexplained variance in capacity in psychosis even after accounting for the contribution of symptoms, that there is good evidence that reducing cognitive biases leads to improvements in psychotic symptoms, that there is preliminary evidence that targeting cognitive biases is linked to improvements in decision making capacity, and that both clinicians and people who experience psychosis believe that retaining or regaining the ability to make decisions about one's care is an important aspect of

recovery. Taken together, this evidence suggests two important hypotheses; first, that cognitive biases may help to explain additional variance in treatment decisional capacity in psychosis over and above that explained by psychotic symptoms and second, that greater treatment decisional capacity may be positively associated with greater self-reported recovery from psychosis. The aim of the current study is to test these hypotheses directly.

Method

Design

This study employed a cross-sectional within-group design. Individuals with psychosis were assessed at a single time-point using self-report questionnaires, structured interviews and other procedures. Ethical approval was granted by the West of Scotland NHS Research Ethics Committee and the University of Edinburgh, after which the study hypotheses and procedures were pre-registered on the Open Science Framework (Larkin & Hutton, 2014). Additional data was collected at baseline from participants taking part in an experimental study, which was running in parallel and administering the same measures to the same population. An initial power calculation was completed during the design of the research. It was predicted that using a large effect size, the study would require 46 participants (as calculated by G*Power) (Erdfelder, Faul, & Buchner, 1996) using an effect size of $f = 0.35$, $\alpha = 0.05$, and power = 0.80 with 6 predictors in a fixed model linear regression. Due to difficulties recruiting to the study, the planned power analysis was modified to test for a change in R^2, and the number of predictors was reduced.

Participants

People were able to take part if they had a diagnosis of non-affective psychosis (ICD-10 F20 – F29 categories), were aged between 18 and 65 and were able to give informed consent to participating in research. Both self-referrals and referrals from clinical teams were accepted.

Those who met these criteria were unable to take part if they had a co-morbid diagnosis of developmental disability, suffered a brain injury or neurological disease, had a primary diagnosis of substance misuse disorder, were non-English speaking (in so far as this prevented them from understanding the questionnaires), were experiencing a crisis or were suffering from acute distress. The inclusion and exclusion criteria were designed to ensure participation, within ethical parameters, of a representative sample of individuals with psychosis. Those with developmental or other comorbid disorders were excluded to increase the internal validity of the findings. Participants were recruited from three NHS Scotland Health Boards; NHS Dumfries and Galloway, NHS Lanarkshire and NHS Lothian, as well as a range of community and voluntary organisations in these areas.

Procedure

Purposive sampling was used to recruit individuals who were in contact with mental health services or third sector organisations. The researcher first presented the research to NHS mental health teams, voluntary organisations, support services and sheltered accommodation services, and permission was given to place posters advertising the study in prominent locations accessible by staff and / or patients. These organisations were asked to identify potential participants, provide them with

an information sheet, which contained full details about the study, and seek verbal consent for the researcher to contact them to discuss the study further.

After confirming that interested individuals met inclusion and exclusion criteria, and after gaining consent to liaise with clinical staff for the purposes of risk assessment, the researcher then met with potential participants in a convenient NHS location to go through the information sheet and discuss the study further. At the second meeting participants' capacity to make a decision about taking part in the research was assessed. Those still eligible were invited to sign a consent form and the study commenced. Potential participants could also self-refer to the study, as long as they provided verbal consent for the researcher to confirm with their clinical team that they met inclusion and exclusion criteria. Research interviews typically took between 90 – 120 minutes, over the course of one or two meetings.

Measures

To characterise the sample, information was gathered on consenting participants' age, gender, ethnicity, education, diagnosis, and illness history. Participants were then invited to complete the following assessments:

MacArthur Competence Assessment Tool – Treatment (MacCAT-T)

The Mac-CAT-T is considered the gold standard in the assessment of decision making capacity (Owens et al., 2009). It is a semi-structured interview that assesses treatment decision making capacity on four dimensions – understanding, appreciation, reasoning, and communication. The MacCAT-T is the most widely used measure of capacity in the literature. Cairns et al. (2005) found that the MacCAT-T produced reliable judgments of capacity, and that clinical judgments of capacity were highly related to Mac-CAT-T scores. The MacCAT-T has been found

to be reliable and valid and to have a high degree of inter-rater reliability (Grisso, Appelbaum, & Hill-Fotouhi, 1997).

Positive and negative syndrome scale (PANSS) (Kay et al, 1987)

The PANSS is a 30-item structured clinical interview. It was designed as a three factor measure to assess positive symptoms, negative symptoms, and general psychopathology. The PANSS is the most widely used measure for the assessment of the symptoms of schizophrenia, and has been demonstrated to have adequate psychometric properties (Kay et al., 1987; Peralta & Cuesta, 1993). Possible scores range from 30 to 210, with a score of 57-61 corresponding to mild illness, a score of 75-78 corresponding to moderate illness, a score of 93-96 corresponding to marked illness, and scores of 115 and above corresponding to severe illness (Leucht et al., 2005). Recently, the PANSS has been investigated as a five-factor measure, as opposed to its original three factor design (Rodriguez-Jiminez et al., 2013). For the purpose of the current research the PANSS was analysed as a five-factor measure, to allow for cognitive impairment to be used as a predictor variable. For exploratory analysis using a mediation model with a variable measuring emotional distress, the pentagonal factor structure of the PANSS (White et al., 1997) was used. The factor and item structure of each of these models of the PANSS is included in Appendix H.

Cognitive Bias Questionnaire for Psychosis (CBQ-P)

The CBQ-P is a 30-item measure designed to measure five cognitive biases – jumping to conclusions, intentionalising, catastrophizing, emotional reasoning, and dichotomous thinking. The CBQ-P has shown adequate psychometric properties, and has been shown to measure an overall thinking style (1-factor model) as well as having a reasonable fit for a 5-factor model, which assesses the cognitive distortions

as separate factors (Peters et al., 2013). The CBQ-P has been used to distinguish clinical and non-clinical voice hearers in a recent study (Daalman et al., 2013).

Beck Cognitive Insight Questionnaire (BCIS)

The BCIS is a 15-item self-report questionnaire that assesses self-reflectiveness and confidence in interpretation of experiences. Several independent groups have demonstrated that the BCIS is reliable, demonstrates convergent and construct validity, and distinguishes patients with psychosis from healthy controls and patients without psychosis (Riggs et al., 2010).

Recovery Assessment Scale (RAS)

The RAS is a 41-item self-report measure of dimensions of service-user defined recovery. It assesses five factors of recovery: hope, meaning of life, quality of life, symptoms, and empowerment. It has been found to be reliable and valid (Giffort et al., 1995).

Probabilistic reasoning task "the beads task"

The beads task (Phillips & Edwards, 1966) is an experimental task designed to examine individuals' reasoning style under conditions of uncertainty. It is based on a Bayesian model of probabilistic reasoning. It has been widely used in studies of people with psychosis and delusions and has been shown to demonstrate a "jumping to conclusions" (JTC) reasoning style, i.e. a tendency to make decisions based on insufficient information (Garety & Freeman, 1999; Freeman 2007; Dudley et al., 2015). A computerized version of the task, as used by Garety et al. (2005) was shown to participants using MS PowerPoint. Variants of this task have used ratios of 85:15 or 60:40. The current study used the 60:40 ratio. While the 85:15 version is simple and maybe more suitable for assessing patients with poor concentration, it may not produce sufficient variation in performance across well-functioning groups.

Those who require two or fewer draws to decision were categorized as evidencing the JTC bias (Dudley et al., 2015), meaning participants will be categorized as having or not having the JTC bias. This variable will be coded "0" or "1" to allow for it to be entered into the proposed regression as a dummy variable.

All measures were administered by AL, who received training and supervision in administration of both the MacCAT-T and PANSS. Anonymised data from the second study was collected by a second researcher (DT), who had also received training and supervision in the use of these measures.

Statistical Analysis

Data were analysed using SPSS Version 21. Bivariate Pearson correlation matrices were produced to examine associations between variables. A series of pre-specified hierarchical linear regressions were conducted using each domain of treatment decision-making capacity as a criterion variable. For each of the three treatment decision making capacity domains, *understanding, appreciation,* and *reasoning* three separate regression models were created. Using the forced entry method, predictor variables that had been shown to be associated with treatment decision-making capacity were entered in one block, then the hypothesised additional predictors of the jumping to conclusions bias and total cognitive biases were entered to explore if these variables contributed to the variance in each domain. Consultation with a senior statistician at the University of Edinburgh confirmed the appropriateness of the statistical plan to test the hypothesised addition of cognitive bias predictor variables.

Post hoc exploratory analyses were also carried out to see if the relationship between the JTC bias and capacity was mediated by positive symptoms, and to test if the relationship between cognitive biases and capacity was mediated by emotional distress. Simple mediation analysis was carried out using the process recommended by Preacher and Hayes (2004, 2008) and Hayes (2013) using PROCESS macros in SPSS version 21.

Service user involvement

The proposed study and methodology was presented to a service user group to get feedback on the acceptability and relevance of the research question, and the feasibility of the research design. Feedback was given by a group of 11 service users with experience of psychosis. Suggestions including word changes to participant information sheets, offering breaks, and allowing participants to bring a friend or family member along to the interview. The study proposal was also presented at a Knowledge Exchange Event with audience members including professionals, researchers, and experts by experience.

Changes to protocol

Some changes were made to the pre-registered protocol during the course of the study, largely due to the challenges in recruiting from a largely rural Health Board. First, recruitment was extended to an urban area (NHS Lothian). Second, the sample size was recalculated and reduced. This was achieved by calculating power to detect a change in the R^2 statistic, and by reducing the number of predictor variables. Using GPower (Erdfelder, Faul, & Buchner, 1996) it was calculated that a sample of 25 participants would have 80% power to detect large effects. Third, additional data was collected at baseline from 8 participants taking part in a parallel experimental study, which was administering largely the same measures (Turner & Hutton, 2015).

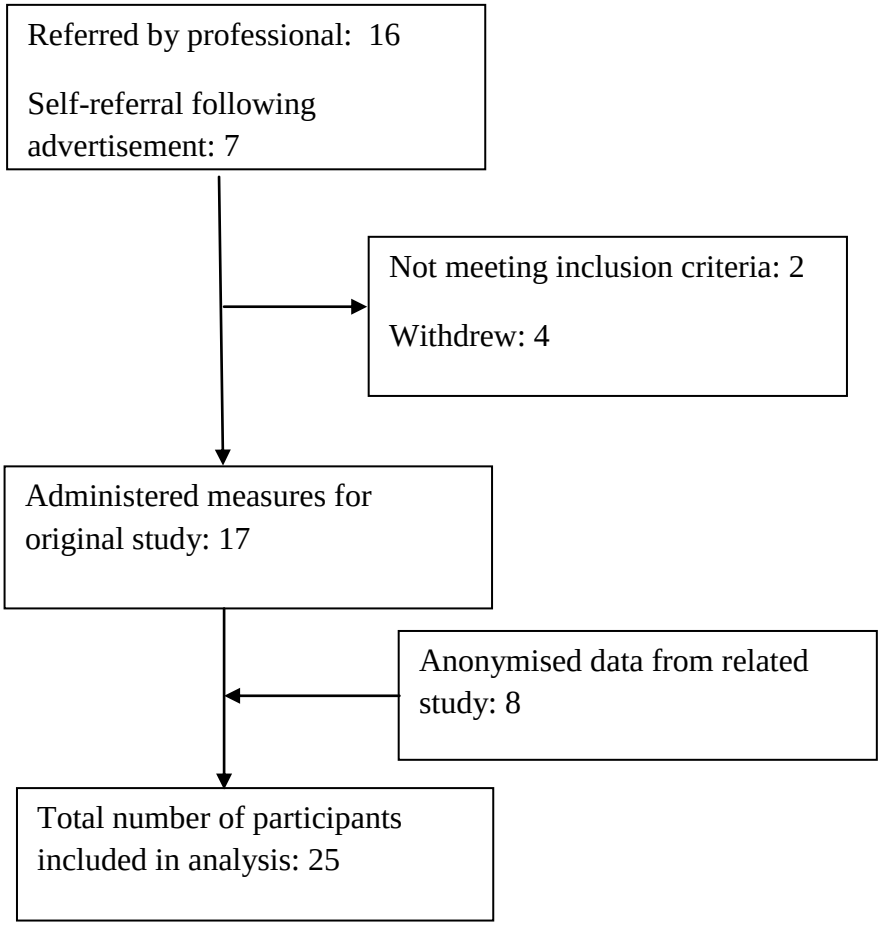
Inclusion of this data meant that the insight item from the PANSS had to be used to measure insight instead of the BCIS. Although BCIS data for those who completed it are still reported below, scores on the PANSS insight item were used for the main regression analyses. Finally, a post hoc mediation analysis was also conducted in order to examine whether emotional distress may mediate the effects of cognitive biases on capacity, as might be predicted by cognitive models of psychosis (Garety et al., 2001; Morrison, 2001). Although post hoc analyses are at risk of various forms of bias (eg hypothesising after the results are known; Kerr, 1998; John et al., 2012), they are regarded as acceptable if they are clearly labelled as post hoc and if they are treated correctly as being exploratory and suggestive rather than confirmatory or hypothesis-testing (Ioannidis et al 2014).

Results

Participant characteristics

As shown in Figure 1, data from 25 participants was included in the analysis; data from 17 were collected by AL and data from 8 were collected by DT (Turner & Hutton, 2015).

Figure 1: Recruitment flowchart



As shown in Table 1, participants were largely male (84%) and were on average approximately 37 years old. Most had received a diagnosis of schizophrenia, with an average duration of illness of approximately 14-15 years ago. Participants were mildly to moderately ill on average, as evidenced by a mean PANSS total score of 71 (Leucht et al., 2005). Just over one third evidenced the 'jumping to conclusions'

decision-making style, as assessed by the Beads task, which is slightly lower than previous estimates (Dudley et al., 2015).

Table 1: Participant characteristics and descriptive statistics

Variables	N = 25
Participant characteristics	**Mean (SD), Median (Range)**
Age	37.63 (11.59), 37 (18 – 62)
Years of education	11.6 (1.8), 12 (9 -14)
Male gender, N (%)	21 (84%)
Years since diagnosis	14.8 (12.2), 13 (0.5 – 41)
Diagnosis	**N (%)**
Schizophrenia, N (%)	19 (76%)
Schizoaffective disorder N (%)	4 (16%)
Psychotic episode N (%)	2 (8%)
Descriptives	**Mean (SD) / N (%)**
MacCAT-T Understanding	3.54 (1.49)
MacCAT-T Appreciation	2.96 (1.06)
MacCAT-T Reasoning	5.08 (2.50)
PANSS Positive Symptoms	12.96 (5.09)
PANSS Negative Symptoms	12.48 (4.00)
PANSS Excited	8.00 (3.27)
PANSS Depressed	8.60 (3.64)
PANSS Cognition	7.56 (1.74)
PANSS Insight	3.12 (2.81)
PANSS Total	71.24 (20.50)
BCIS Self Reflectiveness	14.00 (5.72)
BCIS Self-Certainty	8.47 (5.17)
BCIS Composite Insight	8.24 (7.29)
JTC Draws to decision	5.84 (5.37)
Evidencing JTC bias	9 (36%)
CBQ-P Total	49.00 (13.06)
CBQ-P Intentionalising	9.56 (2.72)
CBQ-P Catastrophising	9.28 (3.01)
CBQ-P Dichotomous Thinking	9.64 (2.83)
CBQ-P JTC	11.36 (3.01)
CBQ-P Emotional Reasoning	9.20 (2.94)
RAS Total	163.29 (26.88)
RAS Personal Confidence and Hope	34.94 (7.12)
RAS Willingness to Ask for Help	12.29 (1.96)
RAS Goal and Success Orientation	20.53 (3.78)
RAS Reliance on Others	15.59 (3.10)
RAS No Domination by Symptoms	11.12 (2.74)

Correlation analysis

Table 2 presents Pearson correlations between variables. Consistent with previous research, all MacCAT-T domains were significantly inversely associated with positive symptoms, cognition and insight, as measured by the PANSS. Large significant inverse correlations were also observed between each domain and the PANSS excitement factor, whereas negative symptoms were only significantly inversely correlated with MacCAT-T understanding ratings. Appreciation and PANSS insight were very highly correlated ($r = .83$, $p < 0.01$), which may suggest a conceptual overlap between the two concepts. Also consistent with previous theory and research, the Cognitive Biases Questionnaire for Psychosis was significantly correlated with depression and positive symptoms as measured by the PANSS, as well as cognitive insight as measured by the BCIS. Average draws to decision on the Beads task was also correlated with the PANSS Excitement factor, as well as overall cognitive biases (as measured by the CBQ-P total score).

Consistent with the study hypothesis, understanding was positively correlated with average draws to decision on the Beads task. Contrary to the hypothesis, however, no significant correlations between MacCAT-T subscales and any other measures of cognitive biases, cognitive insight or subjective recovery were observed. In interpreting these findings, it should be noted that the sample of 25 had 80% power to detect only moderate to large correlations ($r=0.40$ or above). Also, given the early stage of this research we are less concerned about false positive findings (i.e., Type 1 error), and therefore no adjustment for multiple comparisons has been performed.

	MacCAT-T Understanding	MacCAT-T Appreciation	MacCAT_T Reasoning	PANSS Positive	PANSS Negative	PANSS Excitement	PANSS Depression	PANSS Insight	PANSS Cognition	CBQ-P Total	JTC DTD	JTC Category	BCIS SC (N=17)	BCIS SR (N=17)	BCIS Composite (N=17)	RAS (N=17)
Mac-CAT-T Understanding	1.00	.36	**.68****	**-.49***	**-.44***	**-.57****	-.14	**-.44***	**-.52****	-.13	**.48***	-.25	-.17	-.09	.16	.05
MacCAT-T Appreciation		1.00	**.66****	**-.53****	-.23	**-.60****	-.08	**-.83****	**-.50***	-.01	-.01	-.13	-.03	.33	.17	-.17
MacCAT-T Reasoning			1.00	**-.49***	-.33	**-.51****	-.10	**-.55****	**-.46***	-.02	.10	.01	-.14	.15	.16	-.30
PANSS Positive				1.00	**.44***	**.78****	.31	**.60****	**.66****	**.50***	-.24	.11	.45	-.22	-.40	.14
PANSS Negative					1.00	**.49***	.30	.26	**.67****	.34	-.16	.10	.36	-.08	-.29	-.23
PANSS Excitement						1.00	.34	**.69****	**.71****	.35	**-.43***	.39	.13	-.05	-.21	-.02
PANSS Depression							1.00	-.10	.14	**.45***	-.27	.06	-.14	.36	.31	-.38
PANSS Insight								1.00	**.68****	.06	-.13	**.44***	.13	-.22	-.36	.09
PANSS Cognition									1.00	.37	-.23	.39	.38	-.18	**-.52***	-.02
CBQ-P Total										1.00	**-.43***	.12	.32	-.19	**-.54***	-.39
JTC DTD											1.00	**-.58****	.17	-.34	.07	.22
JTC Category												1.00	-.13	.24	-.05	-.20
BCIS Self Certainty													1.00	**-.56***	**-.69****	.27
BCIS Self Reflectiveness														1.00	**.66****	-.20
BCIS Composite															1.00	.06
RAS															.06	1.00

Table 2 Correlation Matrix ***p < .05 ** p < .01**

Table 3 Summary of regression models

	Understanding			Appreciation			Reasoning		
	B	**SE B**	**β**	**B**	**SE B**	**β**	**B**	**SE B**	**β**
Model 1									
Constant	6.30	.96		4.64	.44		9.14	1.59	
PANSS Positive Symptoms	-.07	.07	-.22	-.02	.03	-.11	-.10	.12	-.20
PANSS Negative Symptoms	-.09	.10	-.23	-.04	.05	-.16	-.12	.16	-.19
PANSS Insight	-.15	.24	-.18	-.58	.11	-.96**	-.64	.40	-.45
PANSS Cognition	-.05	.19	-.10	.13	.09	.34	.09	.31	.10
Model 2									
Constant	5.64	1.29		4.61	.55		8.12	2.06	
PANSS Positive Symptoms	-.12	.09	-.41	-.00	.04	-.00	-.10	.15	-.19
PANSS Negative Symptoms	-.09	.10	-.25	-.03	.04	-.12	-.09	.16	-.14
PANSS Insight	-.00	.29	-.00	-.65	.12	-1.06**	-.66	.46	-.46
PANSS Cognition	-.05	.21	-.08	.08	.09	.21	-.08	.33	-.09
JTC bias	-.54	.70	-.18	.56	.30	.26#	1.33	1.11	.26
CBQ-P Total	.02	.03	.21	-.00	.01	-.01	.03	.05	.15
Model Summary	*Model 1 R^2 = .34, Adjusted R^2 = .20, p = .07* *Model 2 R^2 = .38, Adjusted R^2= .18, ΔR^2 = .04, p = .16*			*Model 1 R^2 = .73, Adjusted R^2 = .67, p = .00* *Model 2 R^2 = .77, Adjusted R^2= .70, ΔR^2 = .05, p = .00*			*Model 1 R^2 = .36, Adjusted R^2 = .23, p = .06* *Model 2 R^2 = .43, Adjusted R^2= .24, ΔR^2 = .07, p = .08*		

***p < .01, # p = .08*

The relationship between cognitive biases, symptoms and capacity

A series of hierarchical multiple regression models were used to test whether the JTC bias and cognitive biases contributed to the prediction of the domains of treatment decision-making capacity. A summary of these models is presented in Table 3.

Assumptions of multiple regression analysis

The data used in the analysis and the subsequent regression models were checked to ensure that the assumptions underlying the statistical test had been met. Normal distribution of errors, multi-collinearity, linear relationship between variables, and homoscedasticity were checked as recommended by Osborne and Waters (2002) and Williams, Grajales, & Kurkiewicz (2013). Inspection of histograms, normal P-P plots, and scatter plots as recommended by Fields (2005) revealed residuals that were normally distributed, and no evidence of heteroscedasticity. For the regression models the largest variance inflation factor (VIF) was 4.53, and the average across predictor variables was 2.6. Tolerance statistics ranged from .23 to .67. Menard (1995) suggests that tolerance values below .2 indicate a potential problem, and Bowerman & O'Connell (1990) suggest that a single VIF greater than 10 or an average VIF substantially greater than 1 indicates that the regression model may be biased.

The initial model consisted of factors that had been previously found to be related to treatment decision making capacity; positive symptoms, negative symptoms, insight, and cognition. Predictor variables measuring cognitive biases were then added in the second model. A dummy variable categorising participants into evidencing or not evidencing the JTC bias and the total score on the CBQ-P were added. The initial model accounted for 34%, 73%, and 36% of the variance in the understanding, appreciation, and reasoning domains respectively. This model reached statistical

significance for appreciation only, ($p < .01$). The change in R^2 following the addition of the cognitive bias variables was small, $\Delta R^2 = .04$, .05, and .07 for understanding, appreciation, and reasoning respectively.

The standardised beta co-efficient for the JTC bias in the model predicting each domain was large however, and approached statistical significance in the model of the appreciation domain ($B = .563$, $p = .08$). The inclusion of cognitive biases in Model 2 of appreciation reduced the predictive power of positive symptoms variable, although this did not increase the predictive power of the model. In the appreciation domain the largest predictors of the variance were insight, the JTC bias, and cognition. Consistent with the study hypothesis, this suggests that cognitive biases, and the JTC bias in particular, are related to treatment decision-making capacity, but the effect of cognitive biases may be through the expression of other variables, such as symptoms and emotional distress, as might be predicted by cognitive models of psychosis (Garety et al., 200l; Morrison, 2001).

The partial and zero-order correlations of the models were examined to determine if variables were producing a suppression effect (Cohen & Cohen, 1983). For the reasoning and appreciation models the zero-order correlations between the criterion variables and JTC category were close to zero and partial correlations were larger than the zero-order correlations. These correlations are presented in Table 4. This indicates a suppression effect as defined by Velicer (1968), which occurs when the variance in one predictor variable is reduced by the addition of another variable. An independent variable that contributes little or no variance to the dependent variable may have a large non-zero beta weight because it purifies one or more independent variables of their irrelevant variance, thereby allowing it or their predictive power to

increase (Capraro & Capraro, 2001). This variable shares no variance directly with the dependent variable and thus contributes to the regression equation through removing irrelevant variance from other independent variables. The results of the multiple regression indicate that cognitive biases may act as a suppressor variable for the appreciation and reasoning domains of capacity.

Table 4: Zero-order and partial correlations

	Understanding		Appreciation		Reasoning	
	Zero-order correlation	**Partial correlation**	**Zero-order correlation**	**Partial correlation**	**Zero-order correlation**	**Partial correlation**
PANSS Positive Symptoms	-.49	-.29	-.53	-.00	-.49	-.15
PANSS Negative Symptoms	-.44	-.21	-.23	-.17	-.33	-.12
PANSS Insight	-.44	-.00	-.83	-.78	-.55	-.32
PANSS Cognition	-.52	-.05	-.50	.21	-.46	-.06
JTC bias	-.25	-.18	-.13	.41	.01	.27
CBQ-P Total	-.13	.20	-.01	-.02	-.02	.15

Suppression can occur in the case of an inconsistent mediation relationship between variables (MacKinnon, Krull, & Lockwood, 2000). An exploratory mediation analysis was conducted with positive symptoms as a mediating variable between jumping to conclusions and the domains of capacity to test for this mediating relationship. This analysis was post hoc and exploratory, and it should be noted that the sample in the current study did not have enough power to detect even large effects. According to the sample size calculations provided by Fritz and MacKinnon (2007) a sample seize of at least 36 would have been required.

The results of the analysis are presented in Figures 2, 3, and 4 below. Results indicated that draws to decision had an inverse, but non-significant relationship with positive symptoms (b = -.23, SE = .19, p = .24) in all models.

Positive symptoms had an inverse and significant relationship with understanding (b = -.12, SE = .05, p = 0.03). There was a direct effect of draws to decision on the understanding domain (b = .11, SE = .05, p = .04). The total effect of draws to decision on understanding was significant (b =.13, SE = .05, p = .02). Bootstrapping was used to test the indirect effect of draws to decision on Understanding and this was significant (95% CI 0.00, .08).

Positive symptoms had an inverse and significant relationship with the appreciation domain (b = -.12, SE = .04, p = .01). There was an inverse relationship for the direct effect of draws to decision on the appreciation domain (b = -.03, SE = .04, p = .43). There was no total effect for draws to decision on appreciation (b=.00, SE =.04, p =.97). Positive symptoms had an inverse and significant relationship with the reasoning domain (b = -.24, SE = .09, p = .02). There was an inverse relationship for the direct effect of draws to decision on the reasoning domain (b = -.01, SE = .09, p = .92). The total effect for draws to decision on reasoning (b=.05, SE =.10, p =.63).

This exploratory mediation model indicates that the jumping to conclusions bias has both a direct and indirect effect on understanding through the mediating relationship with positive symptoms, such that the more draws to decision the lower the severity of positive symptoms, and the higher the severity of positive symptoms the lower the scores on understanding. Requiring more draws to decision also has a direct effect on capacity, such that more draws to decision, indicating that the person does not evidence the jumping to conclusions bias, indicate higher levels of understanding. This mediating relationship was not found in the other domains of treatment decision making capacity, appreciation and reasoning.

The small sample size and exploratory nature of the mediation analysis limits our ability to draw conclusions or imply causality; however, these results are in line with the results of the regression model, and lend some initial support for the theoretical cognitive model of psychosis being able to predict variance in treatment decision-making capacity in psychosis, particularly the understanding domain.

Figure 2: Exploratory mediation model - understanding

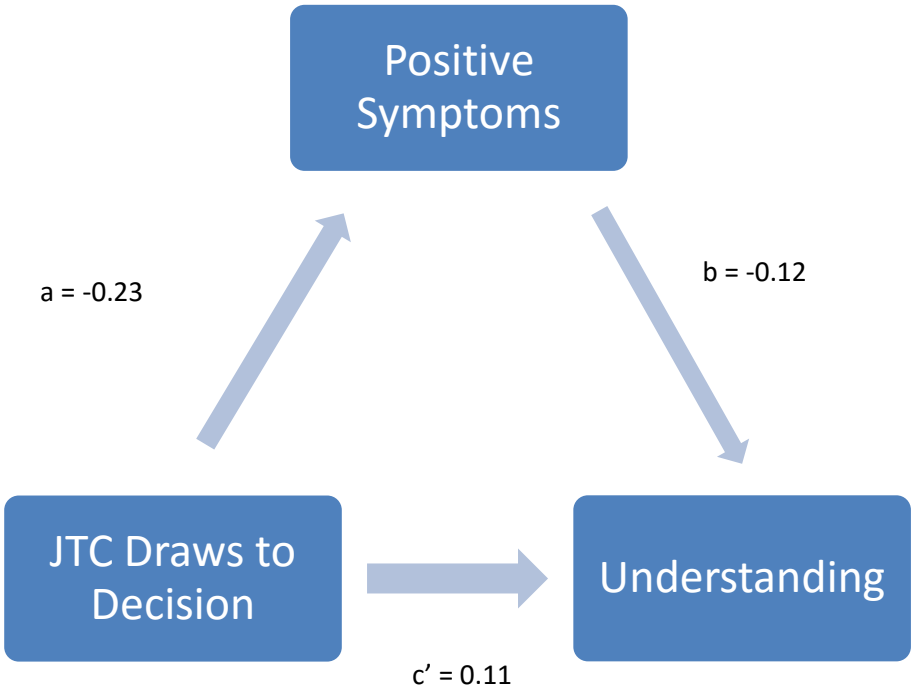


Figure 3: Exploratory mediation model – reasoning

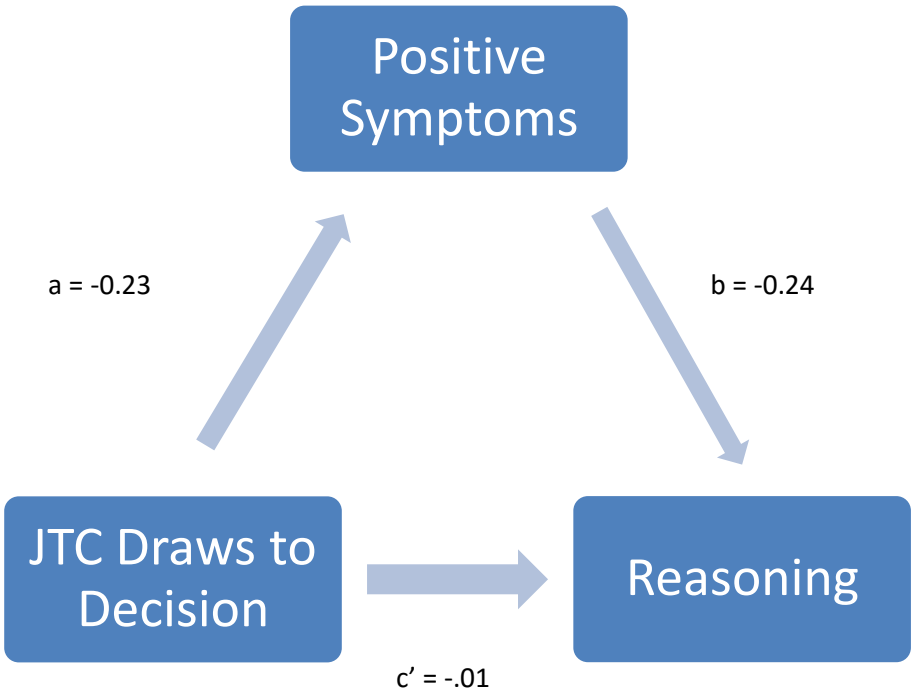
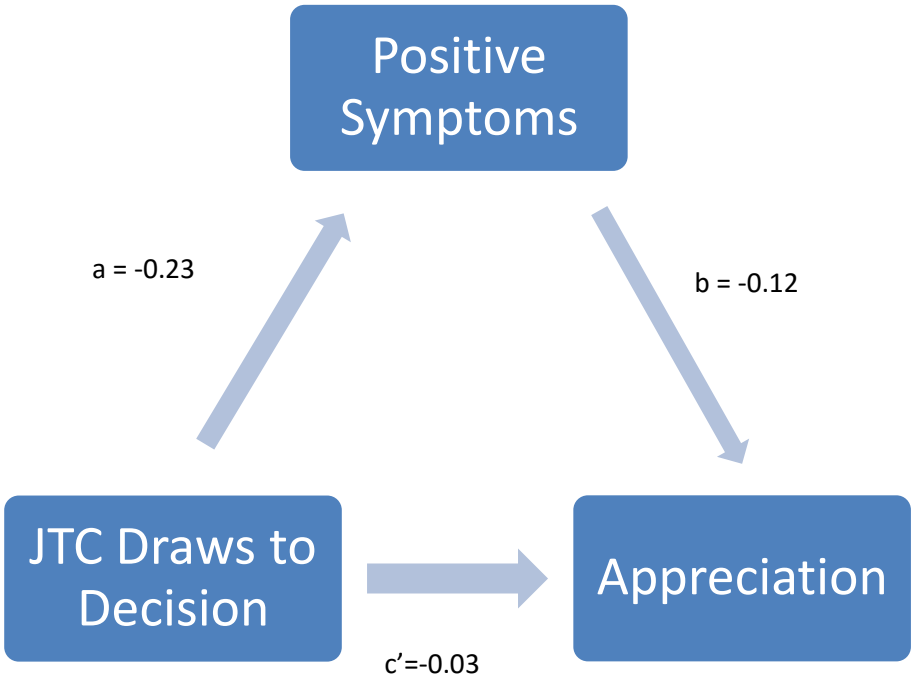


Figure 4: Exploratory mediation model - appreciation



The relationship between capacity and subjective recovery

Contrary to the hypothesis, no correlation between Recovery Assessment Scale (RAS) total scores and domains of decisional capacity were found (see Table 2). However, a correlation matrix was also computed to assess the relationship between the RAS subscales and the three domains of the MacArthur Competence Assessment Tool for Treatment, understanding, appreciation, and reasoning. Although no significant correlations were observed, it is notable that a number of were moderate to large in magnitude and suggestive of a trend towards greater capacity being associated with *reduced* recovery. For example, reasoning appears to have a large inverse albeit non-significant relationship with goal and success orientation. These results are presented in Table 5.

Table 5 Pearson correlations between capacity and recovery (N=17)

	MacCAT-T Understanding	**MacCAT-T Appreciation**	**MacCAT-T Reasoning**
RAS Total	.05	-.17	-.30
RAS Personal Confidence and Hope	.12	-.08	-.17
RAS Willingness to Ask for Help	-.16	-.15	-.35
RAS Goal and Success Orientation	-.13	-.30	-.44
RAS Reliance on Others	.13	.10	-.19
RAS No Domination by Symptoms	.16	-.23	.13

Note: RAS; Recovery Assessment Scale

The relationship between cognitive biases, emotional distress and capacity: Post hoc analysis

A post hoc exploratory mediation analysis was conducted to further explore the relationship between cognitive biases and capacity. Our aim was to explore whether, as predicted by cognitive models of psychosis (Garety et al., 2001), cognitive biases might have an indirect effect on capacity via their effect on emotional distress. Simple mediation analyses were conducted, with cognitive biases as measured by the CBQ-P as the independent variable, domains of capacity as the independent variable, and emotional distress as the mediating variable. A variable for emotional distress was calculated using the pentagonal model of the PANSS (White et al., 1997). An example model of the mediation analysis is depicted in Figure 3.

Results indicated that although cognitive biases were a significant predictor of emotional distress (b = .23, SE = .08, p = .01), emotional distress did not predict scores on the understanding domain of the MacCAT-T (b = -.03, SE = .06, p = .61), the appreciation domain (b = .03, SE = .04, p = .55), or the reasoning domain (b = -.05, SE = .10, p = .65).

There was also no direct effect of cognitive biases on the understanding domain (b = -.01, SE = .03, p = .80), appreciation domain (b = -.01, SE= .02, p = -72), or reasoning domain (b = .01, SE = .05, p = .87).

Figure 5: Exploratory mediation model 2 – understanding

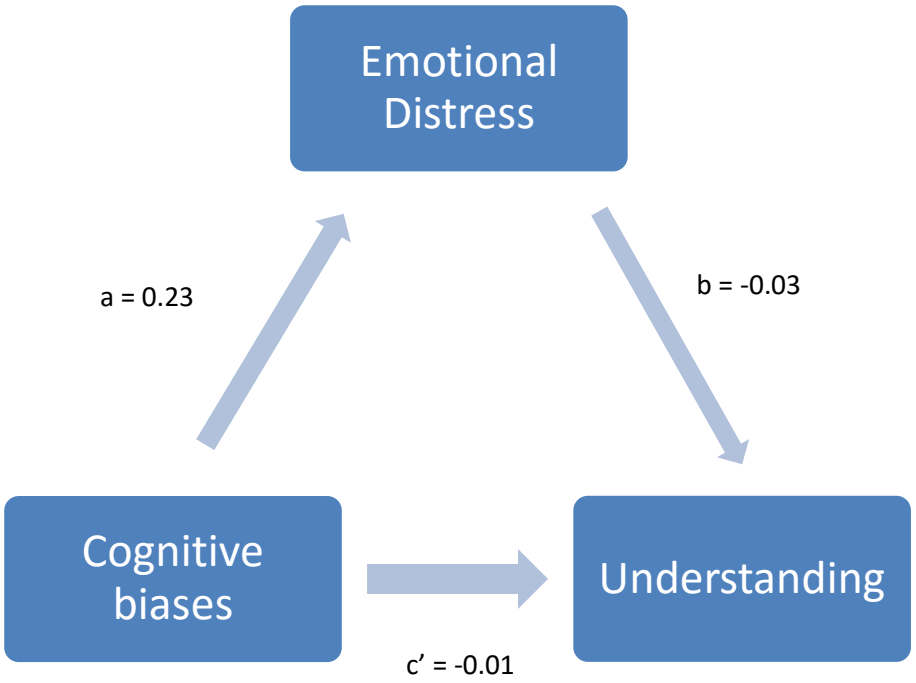


Figure 6: Exploratory mediation model 2 – reasoning

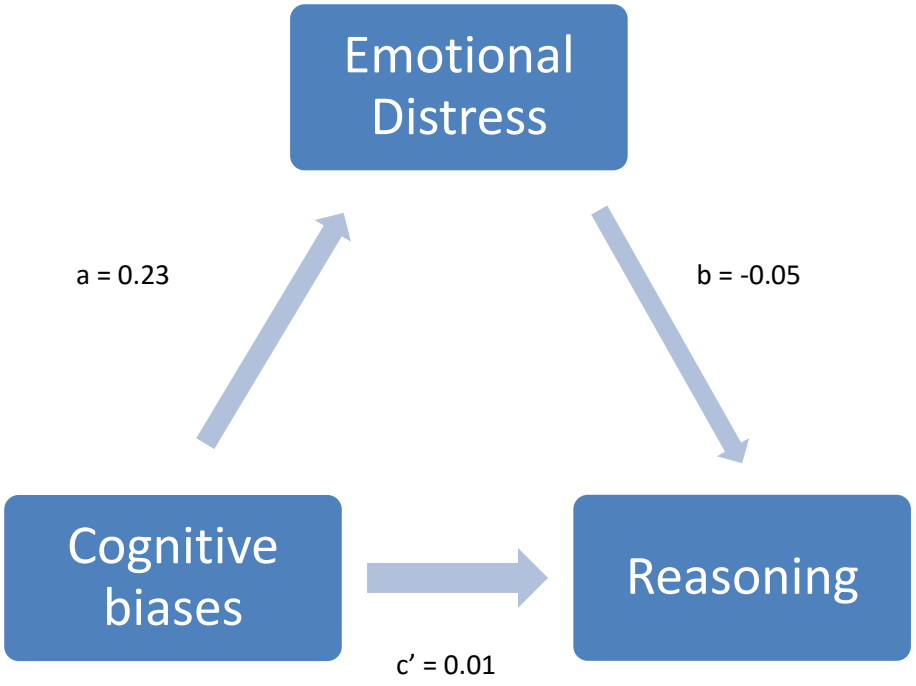
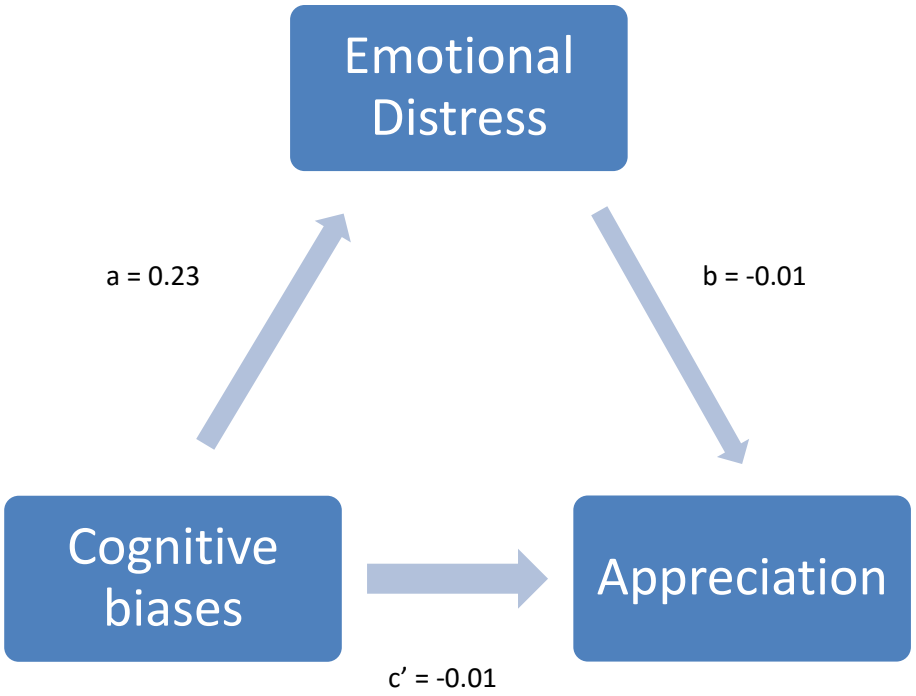


Figure 7: Exploratory mediation model 2 - appreciation



Discussion

Overall, the results of the regression analyses suggest that while cognitive biases and the 'jumping to conclusions' bias may be associated with each of the treatment decision making capacity domains after variance attributable to symptoms, cognition and insight are accounted for, they do not improve the predictive power of the model. In the appreciation and reasoning models, the reduction in predictive power of positive symptoms following the addition of cognitive biases suggests that the hypothesised psychological variables of cognitive biases explain some of the variance in the predictors that had previously been shown to be related to appreciation, i.e. symptoms, cognition, and insight. However, the presence of a possible suppression effect indicates that this relationship may be more complex than the hypothesised relationships tested in the current study. Future research should aim to test these variables being partial mediators of the effect of cognitive biases on capacity, or to use structural equation modelling or path analysis with a larger sample to allow for more complex models of these relationships to be tested.

There was no evidence from this study that recovery as defined by service users with psychosis is positively associated with current conceptualisations of decision-making capacity. Although underpowered, the direction of effect supported the opposite hypothesis; that greater capacity is associated with reduced recovery. Cognitive models of delusions and hallucinations focus on affective processes as well as cognitive processes in understanding psychosis and related distress (Freeman & Garety, 2003; Freeman et al., 2012). As would be predicted by this theory, cognitive biases were related to emotional distress in the mediation analysis. However we found no evidence to suggest that this relationship led to impaired capacity.

Clinical and theoretical implications

This study presents preliminary evidence that cognitive biases may contribute to the variance observed in treatment decision-making capacity in psychosis – either directly or indirectly via their well-established relationship with psychotic experiences (Garety et al., 2013). This study also suggests that psychological variables such as cognitive biases may have different effects on each of the domains of capacity. To the best of the authors' knowledge, this is the first study that has examined the relationship between these variables. Given previous research has shown that psychological therapy, such as metacognitive training (MCT), can change these cognitive biases (Eichner & Berna, 2016), this raises the possibility that capacity, and particularly understanding, may also be modifiable with this approach. Consistent with this, a small study by Naughton et al. (2012) found that MCT was associated with changes in participants' scores on a measure of capacity. However symptoms did not improve in this study, which may suggest that MCT had an effect on capacity via some related yet distinct mechanism. Koren et al (2005), for example, found that metacognitive awareness of cognitive processing was linked to improved decision-making capacity in people with psychosis, and it may be that MCT led to improvements in this domain. Much more research is required to fully understand the relationship between cognitive biases, thinking styles and treatment-decision making capacity in psychosis. As discussed in a recent meta-analysis (van Oosterhout et al., 2016) psychological therapies for psychosis have moved from being predominantly content-oriented and focused on symptoms, to being process-oriented and focus on distress (Garety et al. 2001; Morrison, 2001; Bentall et al. 2009; Bennett & Corcoran, 2010). Research on variables contributing to treatment-

decision making capacity may benefit from a similar process-oriented focus. Longitudinal studies, experimental studies and randomised controlled trials will be required to fully investigate whether such psychological processes have a causal effect on treatment decisional capacity.

Research on service users' conceptualisations of recovery has found that autonomy and empowerment are highly important factors (Law & Morrison, 2014). With this in mind, the high proportion of inverse correlations between participants' recovery and the domains of the MacCAT-T in the current study, albeit non-significant, may point to a problem with the conceptualisation of capacity as it is currently defined. More research is required, but this raises the possibility that trying to improve capacity by trying to promote insight may be associated with adverse effects. If adequately powered studies find such a relationship, there could be significant implications for the existing conceptualisation of capacity, and the design of interventions focused on restoring it. It is also relevant to consider here the recent findings of Capdevielle et al 2009 and Raffard et al 2014, who reported that anxiety was increased in those who had better scores on both appreciation and reasoning. This may not be entirely unexpected if treatment decision-making capacity, as conceptualised in the MacCAT-T, is in fact largely a re-expression of judgements of insight - as might be indicated by the high correlation between appreciation and PANSS insight scores observed in the current study. It is well established that insight is linked to greater emotional distress in psychosis, perhaps because of the stigma attached to this condition (Murri et al., 2016). If a person agrees they have psychosis it may result in a judgement of improved treatment decision-making capacity by their clinician, but the cost may be an increase in emotional distress. A psychological conceptualisation of capacity that is not wedded to a particular diagnostic framework may be better

placed to accommodate the differing narratives that many service users have, and may demand less compliance with dominant psychiatric narratives than current conceptualisations. For a fuller discussion of the problems of basing judgements of capacity on insight, see Allen (2009).

If we take seriously the hypothesis that capacity, as currently defined, may be associated with reduced recovery, then the results of the exploratory mediation analysis, that emotional distress did not mediate a relationship between cognitive biases and capacity begins to make more sense. According to Law and Morrison's (2014) survey of service users with psychosis, there is a consensus that recovery involves being able to cope well with mental or emotional problems. If recovery is inversely associated with capacity – or simply unrelated - then the same may be true for emotional distress and capacity. Further research, with larger samples than the current study, will be required to test these emerging hypotheses.

It should be noted that the interview schedule for the MacCAT-T offered participants a choice between a hypothetical medication and no treatment. This approach does not assess capacity for other choices participants may have made, for example, whether to participate in psychological therapy. This is important because the majority of the participants interviewed for this study referred to coercive and seemingly traumatic previous experiences with medication and choice, and this may have affected their reasoning. This echoes the findings of Stovell and colleagues (2016), and suggests future research on treatment decision-making capacity in psychosis should aim to investigate how previous treatment decision-making experiences within the mental health care system may affect their current choices. Whether individuals who lack

capacity to make decisions about medication may also retain the capacity to make decisions about other treatments is also an important question for future research.

Strengths and limitations

The involvement of service users in the conception and design of this study, as recommended by the British Psychological Society (2004), is a particular strength. This ensured the question was meaningful to service users, and that the design was not overly burdensome. The use of a structured assessment of treatment decision-making capacity is also a strength. The MacCAT-T is the most frequently used instrument to assess treatment-decision making capacity (Cairns et al., 2005), meaning the findings of this study are directly comparable to those produced by other groups. On the other hand, this measure does seem to conflate compliance with an illness model with capacity, and leaves little room for either recovery-focused (Law & Morrison, 2014), emancipatory (Romme & Escher, 1989) or psychological explanations of experiences such as hearing voices (Garety et al., 2001; Morrison, 2001). Adaptations of this measure to accommodate these legitimate perspectives may be required.

The small sample size in this study limits our ability to draw conclusions from the data. The study had 25 participants for the regression analysis. An analysis of power conducted using G*Power V 3.1 (Erdfelder, Faul, & Buchner, 1996), indicates that a sample of 25 participants, as achieved by the current study, had nearly 70% power (1 – α error probability) to detect large effect sizes in a test of R^2 change. However, a larger sample size would have allowed for the detection of smaller effect sizes, and allowed for adequate power to test for possible interaction effects. In addition, the

sample recruited was largely male; although some studies have found that a greater proportion of people with psychosis are male (Ochoa et al., 2012); this may still have had an impact on the generalisability of the results.

The use of hypothetical decisions about medication to assess treatment decision making capacity, as required by the MacCAT-T, may limit the ecological validity of the results. Recruiting participants who are currently making a treatment decision may mitigate this, and may increase the emotional salience of the decision. Previous studies have recruited participants on their admission to hospital to assess their capacity to make these very real decisions (Owen et al., 2009; 2011). Indeed, the MacCAT-T is not often used in clinical practice and so caution is needed before generalising the findings to assessments of capacity that are routinely carried out in clinical practice.

The measure of cognitive impairment in this study was calculated using the five factor model of the PANSS (Rodriguez-Jiminez et al., 2013). While this five factor structure has been validated, future research may benefit from using more direct measures of cognitive performance. Finally, the insight item of the PANSS was used in the regression analysis as a proxy measure of insight and awareness of disorder, however future research would benefit from using measures that are based on a broader conceptualisation of insight.

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Appendix A Search Strategy

The databases Embase, Embase Classic, Medline, and PsycInfo were searched for papers published between 1947 and October 2015.

The terms (Schizo* OR Psychosis) AND (Capacity OR Decision making OR Consent) AND (Treatment OR Health care) were entered into these databases. Results were limited to English language studies and human subjects. Duplicates were removed through placing a limiter on the search.

Studies that were included after full text review were hand searched for relevant studies.

All corresponding authors of included studies were contacted by email to identify any unpublished studies, or extra studies that had not been identified by database search and hand search.

Appendix B Adapted risk of bias tool

We adapted a tool for assessing the methodological quality of observational studies that has been successfully employed in prior research undertaken by the Agency for Healthcare Research and Quality (AHRQ). The main methodological quality criteria were retained but the underlying factors related to each study quality criterion were adapted in some instances for this specific context. Each study is assessed on a number of methodological quality criteria (for example, unbiased selection of groups, sample-size calculations, and so on) that are rated as being met, not met, partially met, or being unclear.

General instructions: Grade each criterion as 'Yes', 'No', 'Partially', or 'Can't tell'. Factors to consider when making an assessment are listed under each criterion. Where appropriate (particularly when assigning a 'No', 'Partially', or 'Can't tell' score), please provide a brief rationale for your decision (in parentheses) in the evidence table.

1. Unbiased selection of the cohort?
Factors that help reduce selection bias:
○ Inclusion/exclusion criteria:
○ Recruitment strategy
- Clearly described.
- Relatively free from bias (selection bias might be introduced, for example, by recruitment via advertisement).

2. Selection minimizes baseline differences in prognostic factors?
Factors to consider:
○ Was selection of the comparison group appropriate?
○ Is the comparison group matched with the clinical group on key demographics (that is age and gender)?

3. Sample size calculated?
Factors to consider:
○ Did the authors report conducting a power analysis or describe some other basis for determining the adequacy of study group sizes for the primary outcome(s) of interest to us?
○ Where a power calculation is presented, do the final numbers obtained match up to this (for example, within 10% of required numbers)?

4. Adequate description of the cohort?
Consider whether the cohort is well-characterized in terms of baseline:
○ Age
○ Sex
○ Ethnicity
○ Diagnosis/clinical status

5. Validated measure of treatment decision making capacity or of domains of treatment decision making capacity?
Factors to consider:

○ Was the method used to assess treatment decision making capacity clearly described (details should be sufficient to permit replication in new studies)?
○ Was a valid and reliable measure used to assess treatment decision making capacity (subjective measures based on self-report tend to have lower reliability and validity than objective measures such as clinical interview)?

6. Validated measures for assessing associated factors of interest?
Factors to consider:
○ Where possible studies should use validated measures to assess factors, for example a validated measure of depression rather than a subjective rating of mood.
○ Were these measures implemented consistently across all study participants?

7. Outcome assessment blind to exposure?
Factors to consider:
○ Were the study investigators who assessed outcomes blind to whether participants had impaired treatment decision making capacity and vice versa?

8. Analysis controls for confounding?
Factors to consider for controlled studies:
○ If groups were not matched as baseline, did the analysis control for any baseline differences between groups?
○ Does the study identify and control for important confounding variables and effect modifiers (for example, IQ)?

9. Analytic methods appropriate?

Factors to consider:
○ Was the kind of analysis done appropriate for the kind of outcome data (categorical, continuous, and so on)?
○ Was the number of variables used in the analysis appropriate for the sample size (the statistical techniques used must be appropriate to the data and take into account issues such as controlling for small sample size, clustering, rare outcomes, multiple comparison, and number of covariates for a given sample size)?

For intervention studies the following additional criteria were rated:

10. Adherence to intervention?
Factors to consider:
- Was the intervention manualised?
- Did all participants receive the same number of sessions / intensity of intervention?

11. Adequate follow-up period?
Treatment decision making capacity is time and decision specific. As such it is expected to change over time. To ensure that the change in capacity can be attributable to the intervention studied, a short follow up period is more valid than a longer follow up period.

Factors to consider:

- How long was the follow up period? Maximum follow up period – 2 weeks

12. Completeness of follow up?

Factors to consider:

- Did attrition from any group exceed 30%? (Attrition is measured in relation to the time between baseline/allocation and outcome measurement. Where different numbers of patients are followed up for different outcomes, use the number followed up for the primary outcome for this calculation.)
- Did attrition differ between groups by more than 10% percent?

Appendix C Cochrane Risk of Bias tool for Randomised Controlled Studies

Domain	Description	Review authors' judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable	Was the allocation sequence adequately
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors *Assessments should be made for each main outcome (or class of*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes)*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and	Were incomplete outcome data adequately addressed?
Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Was the study apparently free of other problems that could put it at a high risk of bias?

Possible approach for *summary assessments* outcome (across domains) within and across studies

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High risk of bias	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of the results.

Criteria for judging risk of bias in the 'Risk of bias' assessment tool

SEQUENCE GENERATION **Was the allocation sequence adequately generated? [Short form: *Adequate sequence generation*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	The investigators describe a random component in the sequence generation process such as: Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: Sequence generated by odd or even date of birth; Sequence generated by some rule based on date (or day) of admission; Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: Allocation by judgement of the clinician; Allocation by preference of the participant; Allocation based on the results of a laboratory test or a series of tests;
Criteria for the judgement of 'UNCLEAR' (uncertain risk of	Insufficient information about the sequence generation process to permit judgement of 'Yes' or 'No'.
ALLOCATION CONCEALMENT **Was allocation adequately concealed? [Short form: *Allocation concealment*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: Central allocation (including telephone, web-based, and pharmacy-controlled, randomization); Sequentially numbered drug containers of identical appearance; Sequentially numbered, opaque, sealed envelopes.

Criteria for the judgement of 'NO' (i.e. high risk of bias).	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: Using an open random allocation schedule (e.g. a list of random numbers); Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); Alternation or rotation; Date of birth; Case record number; Any other explicitly unconcealed procedure.

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgement of 'Yes' or 'No'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS, PERSONNEL AND OUTCOME ASSESSORS **Was knowledge of the allocated interventions adequately prevented during the study? [Short form: *Blinding*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken; Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non- blinding of others unlikely to introduce bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken; Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: Insufficient information to permit judgement of 'Yes' or 'No'; The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Were incomplete outcome data adequately addressed? [Short form: *Incomplete outcome data addressed*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing

Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 'As-treated' analysis done with substantial departure of the intervention received from that assigned at

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: Insufficient reporting of attrition/exclusions to permit judgement of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided); The study did not address this outcome.
SELECTIVE OUTCOME REPORTING **Are reports of the study free of suggestion of selective outcome reporting? [Short form: *Free of selective reporting*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any of the following: The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: Not all of the study's pre-specified primary outcomes have been reported; One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-
Criteria for the judgement of 'UNCLEAR' (uncertain risk of	Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies will fall into this category.
OTHER POTENTIAL THREATS TO VALIDITY **Was the study apparently free of other problems that could put it at a risk of bias? [Short form: *Free of other bias*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	The study appears to be free of other sources of bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	There is at least one important risk of bias. For example, the study: Had a potential source of bias related to the specific study design used; or Stopped early due to some data-dependent process (including a formal-stopping rule); or Had extreme baseline imbalance; or Has been claimed to have been fraudulent; or Had some other problem.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.

Appendix D GRADE Assessment of Quality

Outcomes where more than one study contributed evidence were assessed for overall quality using the GRADE approach. The rating of quality was conducted by the first author, and discussed with second author PH. The following criteria for downgrading were applied to each outcome.

Criteria for downgrading

Study limitations

Individual studies were rated for risk of bias using a tool adapted from Williams et al. (2010). We downgraded by 1 point if three of the parameters in our risk of bias assessment had ≥50% studies with at least one 'no' or 'unclear' rating, and 2 points if four or more parameters had ≥50% studies with ratings of 'no or unclear'.

Imprecision

Imprecision was judged by examining the 95% CI of the effect sizes for the outcome of interest across studies. Optimal sample size was calculated for outcomes, we downgraded 1 point for imprecision when optimal sample size had not been reached, or when 95% CI contained 0.

Inconsistency

For outcomes included in meta-analysis where the I^2statistic was calculated we downgraded by 1 point for inconsistency if the I^2 statistic was ≥40% in the context of an unclear direction of effect or ≥75% in the context of a clear direction of effect. We downgraded by 2 points if the I^2 statistic was ≥75% in the context of an unclear direction of effect.

For outcomes included in the narrative review, we downgraded for inconsistency in cases where 95% CI did not overlap, and heterogeneity could not be explained. We downgraded by 1 point in this case.

Indirectness

The review was exploratory in nature, therefore outcomes had not been pre-specified. However, for outcomes that had used significantly different measures of the same construct, we downgraded by 1 point for indirectness.

Rating up the quality of evidence

In the context of a large effect size, we upgraded by 1 point where the effect size calculated was consistently large. Using Cohen's (1988; 1992) criteria, an effect size of $r \geq .50$ was considered large.

Appendix E

Excluded studies with reasons

Ackerman et al. (2015)	Case description
Ang et al. (2009)	Case description
Baklar (1998)	Editorial
Bingham (2012)	Case description
Bitter et al. (2015)	No measure of capacity
Bowen & Barnes (1994)	No measure of capacity
Bunn et al. (1997)	No measure of capacity
Bursztajn et al. (1991)	Case description
Burton & Twamley (2015)	No measure of capacity
Dudzinski & Sullivan (2004)	Case description
Falzer & Garman (2012)	No measure of capacity
Gray & O'Reilly (2009)	Case description
Grimes et al. (2000)	No measure of capacity
Grisso & Appelbaum (1995)	Comparison of legal standards. No measure of capacity.
Grisso & Appelbaum (1995) (2)	Brief report – no usable data
Hamann et al. (2011)	No measure of capacity
Irwin, Knight, & Pirl (2014)	No measure of capacity
Jacob et al. (2005)	Wrong population
Jeste, Depp, & Palmer (2006)	Review paper
Karel et al. (2010)	Sample <60% psychosis or schizophrenia
Krogsgaard Bording, Munk-Jorgensen, & Puschner (2012)	No measure of capacity

Lee et al. (2010)	No measure of capacity
Linden & Chaskel (1991)	No measure of capacity
Mahone (2004)	No measure of capacity
Mandarelli et al. (2014)	Did not examine relationship between factors and capacity
Maxmin et al. (2009)	Sample <50% psychosis or schizophrenia
McSherry & Bruckard (2009)	Editorial
Meszaros et al. (2011)	No measure of capacity
Moye et al. (2008)	Did not examine relationship between factors and capacity
Parsons & Kennedy (2007)	No measure of capacity
Paul & Oyebode (1999)	Did not examine relationship between factors and capacity
Roth et al. (1982)	Sample <50% psychosis or schizophrenia
Schlecter (2008)	Case description
Seeman (2014)	Case description
Shek, Lyons, & Taylor (2010)	Used SIDMA rather than capacity
Vollman et al. (2003)	Did not examine relationship between factors and capacity
Weinstock, Copelan, & Bagheri (1984)	Did not examine relationship between factors and capacity
Wirshing et al. (1998)	Research decision making capacity rather than treatment decision making capacity
Wirshing, Sergei, & Mintz (2005)	Research decision making capacity rather than treatment decision making capacity

Zalpuri et al. (2015) Case description

Appendix F Ethical Approval

WoSRES

W est of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 4
Ground Floor, Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT
www.nhsggc.org.uk

Date
Direct line 0141-211-1722
Fax 0141-211-1847
e-mail Wosrec4@ggc.scot.nhs.uk

Ms Amanda Larkin
Trainee Clinical Psychologist
NHS Dumfries and Galloway
Department of Psychological Services and Research
Cree West, Crichton Hall,
Dumfries
DG14TG

Dear Ms Larkin

Study title:	**Exploring the role of cognitive biases in treatment decision making capacity of people who have experienced psychosis**
REC reference:	**15/WS/0001**
IRAS project ID:	**149335**

The Research Ethics Committee reviewed the above application at the meeting held on 09 January 2015. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Evelyn Jackson, wosrec4@ggc.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

1. Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions

specified below. .

2. Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. In the Participant Information Sheet:

(a) In section headed "What is the purpose of the study?", the Committee suggested that the third sentence should be reworded – "…..not able to make decisions about their health care….".

(b) In section headed "What are the possible benefits of taking part?", the first sentence should be removed.

(c) In section headed "What will happen to me if I take part?", the Committee suggested that you clarify or remove "or somewhere else" from the sentence relating to where you would meet with the patient.

(d) In section headed "Who is funding and organising this study?", move reference to the research ethics committee to a new section headed "Who has reviewed this study?" and insert the correct name of the REC, i.e. West of Scotland Research Ethics Committee 4.

2. The Committee asked that you uniformly use the term "thinking styles" throughout the paperwork that would be given to study participants.

3. You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

4. It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the

favourable opinion" below).

5. Summary of discussion at the meeting

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Social or scientific value; scientific design and conduct of the study

The Committee noted in the Feedback Sheet for Academic Work from University of Scotland, NHS Scotland, Clinical Psychology Training Programme, that there is reference to recruiting patients who do not have the capacity to consent. However, it was stated in the filter pages and in QA17-2 (exclusion criteria) of the IRAS REC application form that patients who are unable to consent to partake in research would not be recruited to the study.

You confirmed that patients who were unable to consent to partake in research would not be recruited to the study.

The Committee wondered if it was feasible to recruit 46 patients in the relatively short period of time reported.

You explained that you were confident about being able to recruit sufficient numbers and that you had discussed this with Psychiatrists in NHS Dumfries and Galloway. You also explained that should there be a problem recruiting sufficient participants, then you could approach Mental Health services in other Health Board areas.

6. Recruitment arrangements and access to health information, and fair participant selection

The Committee asked for more information as to who would assess a patient to determine if they had capacity to consent to take part in a study.

You explained that key workers in Mental Health Care Teams would assess whether a patient would have the capacity to consent to take part in research and if yes, would ask the patient for permission for you to contact them about the study. When you had contacted the patient and given them the PIS, the patient would have up to a week to decide if they wished to take part. You further explained that if you had any doubts, following this initial contact, about a patient's capacity to consent, then you would not recruit them to the study.

7. Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee wondered if a two hour session would prove burdensome to participants.

You explained that you had taken advice about the length of the session but that would gauge each individual patient and should this be the case, then the session could be split into two x one hour sessions.

8. Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Referrer Poster]	V2	25 November 2014
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Certificate of Insurance]	Version 1	08 August 2014
GP/consultant information sheets or letters [GP letter]	V2	25 November 2014
Interview schedules or topic guides for participants [MacCAT-T Interview Guide]	V1	26 November 2014
Interview schedules or topic guides for participants [PANSS Interview Guide]	V1	26 November 2014
Participant consent form [Participant Consent Form]	V2	20 November 2014
Participant information sheet (PIS) [Participant Information Sheet]	V2	20 November 2014
REC Application Form [REC_Form_02122014]		02 December 2014
Referee's report or other scientific critique report [Assessment from Academic Institution]	Version 1	04 August 2014
Research protocol or project proposal [Research Protocol]	V2	20 November 2014
Summary CV for Chief Investigator (CI) [CV Amanda Larkin (Chief Investigator)]	Version 1	17 October 2014
Summary CV for supervisor (student research) [CV Paul Hutton (Academic Supervisor)]	Version 1	17 October 2014
Validated questionnaire [Beck Cognitive Insight Scale]		
Validated questionnaire [Cognitive bias questionnaire for psychosis]		
Validated questionnaire [Recovery Assessment Scale]		

9. Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

10. After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

11. User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the- hra/governance/quality-assurance/

12. HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/WS/0001	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project. Yours sincerely

Evelyn Jackson

for Dr Brian Neilly Chair

Enclosures: *List of names and professions of members who were present at the meeting*
"After ethical review – guidance for researchers"

Copy to: *Ms Jo-Anne Robertson*
Dr Gwen Baxter, R&D, NHS Dumfries and Galloway

West of Scotland REC 4

Attendance at Committee meeting on 09 January 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Gavin Bell	Managing Intelligence Support Co-ordinator	Yes	
Ms Cristina Coelho	Senior Pharmacist Clinical Effectiveness	Yes	
Dr Clair Evans	Consultant Paediatric and Perinatal Pathologist	Yes	
Dr Michael Fail	Consultant Geriatrician	Yes	
Dr Claire Fang	GP	No	
Dr Ken James	Consultant Anaesthetist	Yes	
Miss Fiona Mackelvie	Retired Administrator	Yes	
Mrs Karen McIntyre	Account Manager, ICON plc	Yes	
Dr Brian Neilly **(Chair)**	Consultant Physician	Yes	
Mrs Linda Renfrew	Consultant Physiotherapist in MS	Yes	
Dr Subra Viswanathan	Consultant GI Radiologist	Yes	
Mr John Woods		Yes	
Mr Iain Wright	Self Employed	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Judith Godden	Scientific Adviser
Ms Evelyn Jackson	REC Manager

Appendix G Consent Forms and Participant Information Sheets

Study Information

Study title: Exploring cognitive biases in the treatment decision making capacity of people who have experienced psychosis.

We would like to ask you to take part in our research study. Before you decide we would like you to know why the research is being done and what it would mean for you.

One of our team will meet with you to go through the information sheet with you and answer any questions you have. This should take about 10 – 15 minutes.

Talk to other people about the study if you want to. You can contact the research unit of NHS Dumfries and Galloway if you want to talk about the study with them. You can also contact Kaleidoscope, the Dumfries branch of Support in Mind Scotland. These people are not connected with this research, and can talk to you independently of the research team.

Dumfries & Galloway

Research & Development
Support Unit
Dumfries & Galloway Royal
Infirmary
Bankend Road
Dumfries
DG1 4AP

Tel: 01387 241165

Support In Mind Scotland
Kaleidoscope
Mountainhall
Bankend Road
Dumfries
DG1 4AL

Tel: 01387 249513
Email:
kaleidoscope@supportinmindscotland.org.uk

What is the purpose of this study?

We are doing this study to see if thinking styles (also known as cognitive biases) are linked to whether or not someone is able to make decisions about their health care. Thinking styles have been shown by other research to be involved in psychosis. People who have experienced psychosis are more likely to not be able to make decisions about their health care than other people. We want to see if thinking styles are linked to decision making ability. We will ask you about thinking styles, symptoms, and what you think about your disorder. We also want to see if decision making ability is linked to recovery.

Why are you asking me to take part?

We have asked you to take part in the study because you are aged between 18 and 65 years, because you have had psychosis, and because you have been told you have a psychotic disorder.

Do I have to take part?

No, you do not have to take part. It is up to you if you take part in this study. If you want we will meet with you to talk about the study. We will go through this information sheet. If you agree to take part we will then ask you to sign a form. This form says that you agree to take part. You can stop taking part at any time, without saying why. Taking part in this study will not affect your health care.

What will happen to me if I take part?

We will meet with you to ask some questions, and do a computer task. First we will talk to you about the study, and ask for your consent to take part. If we're not sure that you understand the consent fully, we will talk to your key worker about it to make sure.

After you give consent, we will ask you some questions about decision making, and some questions on symptoms and your experiences. You will then be asked to look at a computer screen and answer a question based on what's on the computer screen.

We should only need to meet with you once. It will take about two hours. You can take breaks when you like. We can meet you at a health centre, or at home. You can bring someone with you, if you like.

If you want to take part, we will let your GP and health care team know.

What will I have to do?

If you want to take part, you will have to meet with us once. You will be asked to answer some questions, and look at a computer task.

What are the possible disadvantages and risks of taking part?

We don't think that there will be anything bad about taking part. You might get tired. If this happens, you can take a break. You might find some things hard to talk about. If this happens, you can take a break, or we can talk about what has come up for you. You might find it hard to come along to an interview. We will try to make it as easy as we can for you.

What are the possible benefits of taking part?

We want to know about your experiences and thoughts on things. You might not notice any benefit. We hope that this study will benefit people like you in the future. It will be good for doctors to know more about decision making ability.

What will happen if I don't want to carry on with the study?

We will only need to meet with you once to carry out the study. If you decide that you don't want to carry on, we will stop. If you decide after we have done the interview that you don't want to take part, you can let us know. We will take your information out of the study. There will be no difference to the health care you receive if you don't want to continue with the study.

Will people know what I say?

Personal records will be kept in a locked filing cabinet in an NHS office. You name will not be put on any of the records that we collect. This means that no one will be able to tell that it came from you. Once we have finished the study, anything with your name on it will be shredded. Records without your name will then be stored on computers at the University of Edinburgh.

What will happen to the results of the study?

You will receive a copy of the results once the study has finished. The results will be published in a science journal, and they will be presented to service users and professionals. Your name will not appear anywhere in the results. The study will also be handed in to the University of Edinburgh to be marked.

Who is funding and organising this study?

The study is funded by the NHS and the University of Edinburgh. The West of Scotland Research Ethics Committee 4 has reviewed and approved this study.

If I want to take part, what do I do next?

If you want to take part, tell your keyworker. They will give us your details. We will contact you to talk about the study and arrange a time to meet with you.

The researcher, Amanda Larkin, will meet with you to go through the study details and get your consent to take part. You will have at least a week to think about the information on this sheet before we meet with you. You will be asked to sign a form to say that you want to take part, and to make sure that you know what the study involves. We will also let your GP know that you are taking part in the study.

What if I'm not happy with what happens?

You can drop out of the study at any time, by contacting us using the details below.

If you have any more questions about the study you can ask Amanda Larkin

TEL: 01387 244495

EMAIL: amanda.larkin@nhs.net

The full contact details for the people doing this research are:

Chief Investigator

Amanda Larkin,
Trainee Clinical Psychologist,
Department of Psychological Services and Research,
Crichton Hall,
Bankend Road,
Dumfries,
DG1 4TG
01387244495
amanda.larkin@nhs.net

Supervisors

Dr Paul Hutton,
Chancellor's Fellow and Clinical Psychologist,
University of Edinburgh,
School of Health in Social Science,
Doorway 6,
Medical Building,
Teviot Place,
EH8 9AG
paul.hutton.cf@ed.ac.uk

Dr Katie Whyte,
Clinical Psychologist,
Department of Psychological Services and Research,
Crichton Hall,
Bankend Road,
Dumfries,
DG1 4TG
01387244495
jstirling@nhs.net

Thank you for taking the time to read this information sheet

If you wish to make a complaint about the study please contact

Patient Services Team
NHS Dumfries and Galloway
Logan West
Crichton Hall
Dumfries
DG1 4TG
01387 272733

CONSENT FORM

Study Title: Exploring cognitive biases in treatment decision making capacity of people who have experienced psychosis.

Name of Researcher: Amanda Larkin (Trainee Clinical Psychologist, NHS Dumfries and Galloway and University of Edinburgh)

Participant ID: _____

Please initial in the box if you agree with the sentence:

1. I have read and understand the information sheet dated..... (version.....) for the above study. I have thought about what it says. Any questions I asked have been answered.	
2. I understand that taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I know that some interviews will be recorded. I understand that these interviews will be recorded and written out word for word. I give permission for this to be done. I understand that these recordings will be destroyed once the interviews have been analysed.	
4. I agree to my GP being told that I am in the study. All the information I provide in the study will be anonymous and confidential. However, if I reveal information about future harm to myself, or others, that information will be passed on to the appropriate healthcare professional.	
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the regulatory authorities and from the University of Edinburgh or from NHS Dumfries and Galloway where it is relevant to my taking part in the research. I give permission for those individuals to have access to my records.	
5. I agree to take part in the above study.	

Name of Participant: _____

Date: _____

Signature: _____

Name of Person taking consent: _____

Date: _____

Signature: _____

Original (x1) to be retained in site file
Copy (x1) to be retained by the participant

Appendix H Measures used in the study

MacCAT-T Interview Schedule

I am going to ask you some questions about a possible, hypothetical treatment. This discussion is just for the purpose of this interview and will not affect your actual treatment. First, I will describe to you what I believe is the problem. Then I'll talk to you about the research treatment, and the possible risks and benefits. I will ask you to apply that information to yourself, and then I'll ask you to make a decision about whether you would or would not want to take this medication if it were offered to you.

Understanding disorder

Disclosure

1. Diagnosis
2. Feature of disorder
3. Feature of disorder
4. Feature of disorder
5. Course of disorder

Now please explain in your own words what I've said about your condition.

Re-disclose and re-enquire if necessary.

Appreciation-disorder

Now that is what I think is the problem in your case. If you have any reason to doubt that, I'd like you to tell me so. What do you think?

Understanding-treatment

Disclosure

1. Name of treatment: Medicine 1
2. Feature of treatment: It can be taken as tablets or liquids twice a day
3. Feature of treatment: You will start at a low dose and increase until we find the right dose for you.
4. Feature of treatment: You ought to stay on the medication for at least 2 years and see your doctor once a month

Now please explain in your own words what I've said about this treatment

Re-disclose and re-enquire if necessary.

Understanding-benefits/risks

Disclosure

1. Benefit: It will make your symptoms less troublesome
2. Benefit: It will reduce the risk of relapse. With treatment 15% relapse. Without treatment 57% relapse
3. Risk: There is a low risk that you may experience problems such as abnormal movements of your mouth and tongue, which you cannot control.
4. Risk: There is a moderate risk that you may experience problems with weight gain

Now please explain in your own words what I've said about benefits and risks of this treatment.

Re-disclose and re-enquire if necessary.

Appreciation-treatment

You might or might not decide that this is the treatment you want – we'll talk about it later. But do you think it's possible that this treatment might be of some benefit to you?

So you feel that it is / isn't possible for this treatment to be of some help for your condition. Can you explain that to me? What makes it seem that the treatment would / wouldn't be of possible benefit to you?

Alternative treatments

Disclosure

1. Name of treatment: No treatment
2. Feature of treatment: You do not have to take any tablets
3. Feature of treatment: You will need to continue seeing a doctor or nurse or psychologist every month
4. Feature of treatment:You ought to continue attending the service for at least 2 years

Now please explain in your own words what I've said about this treatment

Re-disclose and re-enquire if necessary.

Understanding-benefits/risks

Disclosure

1. Benefit: You do not have to take any tablets.
2. Benefit: There is no risk of weight gain.
3. Risk: The likelihood is your symptoms will continue without treatment
4. Risk: There is a high risk of relapse. Without treatment 57% of patients relapse within a year.

Now please explain in your own words what I've said about benefits and risks of this treatment.

Re-disclose and re-enquire if necessary.

First choice and reasoning

Now let's review the choices that you have. First ....: second..... Which of these seems best for you? Which do you think you would be most likely to want?

You think that (state patient's choice) might be best. Tell me what it is that makes that seem better than the others.

Discuss explanation to explore reasoning process.

Generate consequences

I told you about some of the possible benefits and risks or discomforts of (name the patient's preferred treatment option). What are some ways that these might influence your everyday activities at home or at work?

Now let's consider (no-treatment option). What are some ways that the outcomes of that option might influence your everyday activities at home or at work?

Final choice

When we started this discussion you favoured (insert First Choice from earlier enquiry, or note that the patient seemed to be having difficulty

deciding). What do you think now that we have discussed everything? Which would you want to do?

Logical consistency of choice

Examiner's explanation.

PANSS Interview Guide

I've got a list of questions here which we ask people who have had problems with their mental health. I ask everyone the same questions so some of them might not apply to you. I need to know mainly how you have been feeling over the past week.

P.1 Delusions

When you are by yourself what do you think about?
What about imagining things that aren't true?
Some people have told me in the past that sometimes they feel that messages are directed to them from the TV or the radio, do you ever experience anything like that?
Do you ever have thoughts that interfere with your thinking?
How often do these things happen to you? Do these experiences affect your behaviour?
Has this happened in the last week?

P.2 Conceptual disorganisation – *based on observation of behaviour during the interview.*

P.3 Hallucinatory behaviour

Do you ever have strange experiences? Hear strange noises?
Do you sometimes hear things that others don't hear?
Do you sometimes receive personal communications from the radio or television? From God?
Do you sometimes hear voices inside your head? When? How often? Have you heard them today? How clear are they? How loud are they?
Do the voices belong to someone you know? Who are they? How many are there? Do they speak to you, comment about you, or speak to each other?
What do the voices say? Are they good or bad voices? Are you afraid of them?
Do the voices tell you what to do? Give you direct orders?
Do you obey the voices' commands? Must you?
Do ordinary things ever appear strange or distorted?
Do you ever have visions or see things that others don't? How often? How clear are these visions?
Do the visions occur together with the voices or separately?
Do you ever smell things that others don't?
Do you get strange sensations from within your body or feel something strange inside you?
What do you make of these voices / visions / smells / etc.? Are they a problem for you?

P.4 Excitement

Do you ever feel “hyped-up” or agitated? Tell me about it

P.5 Grandiosity

Do you think you are special in some way?
Have you had any thoughts recently about having special powers, or being more important than other people?
How do you compare to the average person? Better or worse?
Do you have talents or abilities that most people don’t have?
Do you have ESP? Can you read another person’s mind?
Do you have special or unusual powers?
Do you have a special mission in life? How did this come about?
Are you a religious person? What is your relationship with God? Are you closer to God than others are? Are you one of God’s angels / children?

P.6 Suspiciousness / Persecution – *rated on thought content expressed in the interview and its influence on behaviour.*

P.7 Hostility

Do you feel irritable?
What sort of things irritate you?
What do you do if you feel irritated?
Do you ever argue with people?
Do you ever get angry with people, or shout at people?

N.1 Blunted affect – *rated on observation during the interview*

N.2 Emotional Withdrawal

How do you feel in your spirits?
What do you do during the day? Do you have any hobbies?
Do you go out at all? Who with?
Do you have anyone to talk to about your problems? Do you think they understand?
When you go out, do you usually only go if someone asks you to out with them?
Do you ever call on family or friends and ask them if they would like to go out?
Do your family and friends take an interest in your problems?
Do people ever come and discuss their problems with you?

N. 3 Poor Rapport – *based on observations of behaviour during the interview*

N. 4 Passive / Apathetic Social Withdrawal

Is there anything that would stop you going out? How often does this happen?
What sort of things interest you?
How is your energy?
Do you ever feel like you can't be bothered to do anything? How often? What causes this?
When you are with other people do you have a conversation with them? Why?
How much time do you spend on your own? Why?

N.5 Difficulty in Abstract Thinking

Do you ever have difficulty explaining things?
Do you ever have difficulties with your thinking?
Can I test your memory a bit? Do some proverbs / similarities?
Proverbs – have you heard this before? What does it mean to you?

- Plain as the nose on your face
- Carrying a chip on your shoulder
- Two heads are better than one
- Too many cooks spoil the broth
- Don't judge a book by its cover
- One man's food is another man's poison
- All that glitters is not gold
- Don't cross the bridge until you come to it
- What's good for the goose is good for the gander
- The grass always looks greener on the other side
- Don't keep all your eggs in one basket
- One swallow does not make a summer
- A stitch in time saves nine
- A rolling stone gathers no moss
- The acorn never falls far from the tree
- People who live in glass houses shouldn't throw stones

Similarities – how are _____ and _____alike?

• Ball and orange • Apple and banana • Pencil and pen • Penny and pound • Table and chair • Tiger and elephant • Hat and shirt • Bus and train	• Arm and leg • Rose and tulip • Uncle and cousin • The sun and the moon • Paintings and poems • Hilltop and valley • Air and water • Peace and prosperity

N. 6 Lack of Spontaneity and Flow of Conversation – *based on observations during the interview*

N.7. Stereotyped Thinking – based on observations during the interview

G.1. Somatic Concerns

How have you been feeling?
Is there any problem with your physical health?
How is your head? How is your heart?
Any trouble with any part of your body?
Does your head or body ever feel strange?
What is causing these problems?
Have you seen the doctor about these problems?
Do you have any medications for these problems? If not, why not?

G.2. Anxiety

Do you ever get anxious / worried about things?
Have you ever had panic attacks?
Have you been feeling nervous or tense?
Would you please hold your hands out straight? (inspect for tremor)
How anxious have you been feeling?
Do you ever get into a state of panic?
Have your worries or nervousness affected your sleep? Your appetite? Your ability to work?
Does your heart race?
Do you get butterflies in your stomach?
Has it happened in the last week? How often?

G.3. Guilt Feelings

Do you get into moods where you blame yourself for things, feel guilty or down on yourself? About things in the past?
Do you feel less worthwhile than the average person?
Do you consider yourself a bad person in some ways?

G.4. Tension

Do you get tense? How often?
What does that feel like? Do your muscles get tight?
Do you ever get feelings of tension and stiffness in your muscles?

G.5 Mannerisms and Posturing - based on observations of behaviour during the interview

G.6. Depression

How have you been feeling in your mood / spirits in the last few days?
Have you felt bad in yourself, down in the dumps?
What is your typical mood like?
Are you mostly happy? Sad? Why?
How unhappy have you been feeling?
When do you feel the saddest? How long do these feelings last?
Do you sometimes cry? How often?
Has your mood affected your appetite? Your sleep? Your ability to work / concentrate?
Have you had any thoughts of harming yourself or ending your life?
How do you see your future?
Do you get feelings of worthlessness or hopelessness?

G.7. Motor Retardation – based on observations during interview

G.8. Uncooperativeness

Do you attend a day hospital?
How often do you go? Do you enjoy going?
Do you ever do odd jobs around the house or for your family and friends?
Do you take your medication regularly? If not, why not?
Do you keep your appointments with your doctor or psychiatrist? How often do you miss them? Why?

G.9. Unusual Thought Content – ratings based on behaviour and reported thought content during interview

G.10. Disorientation

I'd like to ask you some questions about your orientation?
Do you sometimes forget the date / your address / names?
Do you ever feel confused and not know where you are?
What day of the week is it? What is today's date? What season are we in?
Where are we now located?
What is the name of your doctor / psychiatrist?
Who is the Prime Minister?

G.11. Poor Attention

How long can you focus your attention? How long could you watch TV, read the newspaper, etc? Could you watch a film all the way through?
Are you distracted by things easily?

G.12. Lack of Judgement and Insight

Are you in need of treatment?
Do you have a psychiatric disorder? Have you had one in the past?
What are the symptoms of your illness?
Why are you taking medicine?
What are your immediate plans for the future?
What is your diagnosis?
Do you agree with it?
What have you been told about your illness? Do you agree with this? Why?

G.13. Disturbance of Volition

What is your explanation for the things happening to you?
Do you feel like you've got drive to get up and do things of your own accord?
If you got thirsty, would you go and make yourself a drink?
Do you feel able to make decisions?
Do your thoughts ever make it difficult for you to make decisions?
Do you sometimes forget what you are doing?

G.14. Poor Impulse Control

Do you think that you are predictable?
Do you do things on impulse sometimes?
Do you ever break things if you lose your temper?

G.15 Preoccupation – based on interpersonal behaviour observed during the interview

G.16. Active social avoidance – rated based on answers to previous questions

Cognitive bias questionnaire for psychosis

Cognitive Biases Questionnaire for Psychosis (Peters et al., 2013)

Instructions: In this questionnaire you will find a number of descriptions of everyday events. After each situation are different ways that people might react, labelled A, B, or C. Please imagine yourself in each situation as vividly as possible.

Once you have imagined that the event is happening to you, please choose the option that best describes how you might think about the situation. If none of the options matches completely how you might react, choose the one which is the closest. If more than 1 option applies, choose the one which would run through your mind most often. When you have decided which option you are most likely to think, put a circle around the letter next to it. There are no right or wrong answers. Work through the questions fairly quickly, making sure you pick the option that is nearest to what your immediate reaction might be.

1. Imagine you receive a letter and you notice it is not sealed.

I am most likely to think: (please circle A, B, or C)

A. Somebody has deliberately opened this letter already.
B. I wonder if this may have been opened again after it was written.
C. I don't think anything of it.

2. Imagine that you are walking down the street when you hear your name being called, but when you look around you don't see anybody.

I am most likely to think: (please circle A, B, or C)

A. Something strange is going on.
B. There is something really dangerous about this.
C. I must be imagining things.

3. Imagine your food tastes different from usual.

I am most likely to think: (please circle A, B, or C)

A. Someone may have done something to my food on purpose.
B. This food must have been prepared with a different ingredient today.
C. Someone has deliberately spiked my food.

4. Imagine that on your way to work you notice that all the traffic lights turn red as you approach them.

I am most likely to think: (please circle A, B, or C)

A. It's going to take me longer to get in this morning.
B. That's all I need, I'm going to be really late now.
C. My day is going to be ruined.

5. Imagine you are standing at a bus stop when the bus you have been waiting for drives past half empty without stopping.

A. People are always so nasty.
B. People aren't very nice sometimes.

I am most likely to think: (please circle A, B, or C)

C. The driver must be in a bad mood today.

6. Imagine you have a really bad pain in your head.

I am most likely to think: (please circle A, B, or C)

A. There must be something wrong with me.
B. There's lots of different reasons why I might have this pain.
C. I must have something really serious, like a brain tumour.

7. Imagine that while on the bus, you notice a stranger staring at you.

I am most likely to think: (please circle A, B, or C)

A. The way this person is staring at me is a bit worrying.
B. This person must mean me harm to be staring at me that way.
C. This person is being really rude to be staring at me in that way.

8. Imagine you are sitting at home and you suddenly feel very odd.

I am most likely to think: (please circle A, B, or C)

A. I wonder why I feel odd, could something sinister be going on somewhere.
B. This feeling is proof there is something bad happening somewhere to someone I know.
C. I must be overtired or something.

9. Imagine you applied for a job and did not get it.

I am most likely to think: (please circle A, B, or C)

A. Perhaps I can get some feedback about why I did not get the job.
B. I wonder if I did not do very well at the interview.
C. I'll never be able to get a job.

10. Imagine that you are on a train when you suddenly have a strong feeling you have been there before.

I am most likely to think: (please circle A, B, or C)

A. This is some kind of premonition that something awful has happened or will happen.
B. I wonder if this is some kind of premonition.
C. This is a weird, but common experience.

11. Imagine you get turned down to go out by someone you like or a friend.

I am most likely to think: (please circle A, B, or C)

A. I quite often get rejected in this situation.
B. You win some, you lose some.
C. I always get rejected for anything I try.

12. Imagine that one day you enter a shop and you hear people laughing.

I am most likely to think: (please circle A, B, or C)

A. They must be laughing at me.
B. I wonder if they are laughing at me.
C. The laughing is probably nothing to do with me.

13. Imagine there are police cars outside your house. You suddenly realise you feel uncomfortable.

I am most likely to think: (please circle A, B, or C)

A. Funny how just seeing the police has this unsettling effect on people.
B. I wonder why I feel so uncomfortable, could the cars be something to do with me.
C. I must have done something wrong to feel so uncomfortable, they've come to get me.

14. Imagine you are watching television, and suddenly the screen goes blank.

I am most likely to think: (please circle A, B, or C)

A. Weird things are always happening.
B. This sort of thing seems to happen quite a lot.
C. There must be something wrong with the TV today.

15. Imagine two people in a queue at the supermarket both look your way at the same time and then immediately start to talk to each other.

I am most likely to think: (please circle A, B, or C)

A. This is not the first time this has happened.
B. This sort of thing can happen in queues.
C. This always happens wherever I go.

16. Imagine you are waiting in a cafe for an acquaintance to arrive, and you suddenly feel a strange shivery feeling inside.

I am most likely to think: (please circle A, B, or C)

A. Feeling shivery is a bad omen, I don't think I should meet this person.
B. I must be nervous about meeting this person.
C. I wonder if feeling shivery means something bad might happen.

17. Imagine you think you see a shadowy figure moving across the wall of an empty room.

I am most likely to think: (please circle A, B, or C)

A. I wonder what that was.
B. My eyes must be playing tricks on me.
C. There must have been someone or something there.

18. Imagine that the phone rings. When you answer, the other party hangs up.

I am most likely to think: (please circle A, B, or C)

A. I wonder if there's something suspicious about this.
B. Somebody is definitely checking up on me.
C. Someone's probably got the

wrong number.

19. Imagine you are watching the news on TV about a recent disaster, and you find yourself feeling guilty.

I am most likely to think: (please circle A, B, or C)

A. If I feel guilty, I must be responsible in some way.
B. It's normal to feel guilty when a disaster has happened to someone else.
C. I wonder why I feel guilty, maybe I'm unwittingly responsible in some way.

20. Imagine you are listening to the radio and suddenly there is crackling interference.

I am most likely to think: (please circle A, B, or C)

A. Someone has deliberately tampered with my radio so that it is no longer tuned properly.
B. I wonder if someone has been fiddling with my radio.
C. There is some sort of interference on the radio waves.

21. Imagine that you are sitting on a train, and you think you can hear two people behind you talking about you. When you look round, they are reading their papers and not talking to each other.

I am most likely to think: (please circle A, B, or C)

A. They were definitely talking about me, they're just pretending to read their paper.
B. I'm sure I heard them talking about me, maybe I was wrong.
C. I should find out if anyone else ever has this kind of experience before deciding what really happened.

22. Imagine you are at home; everything is quiet when you hear a sudden fast banging on the walls.

I am most likely to think: (please circle A, B, or C)

A. The neighbours are doing this deliberately to upset me.
B. The neighbours could be doing some kind of home improvement.
C. The neighbours must be trying to tell me something.

23. Imagine you are reading a newspaper or magazine, and you read an article that has some special relevance to you.

I am most likely to think: (please circle A, B, or C)

A. This article seems to have been written with people like me in mind.
B. I wonder if someone may have written this article for me.
C. Someone has definitely written this article for me specifically.

24. Imagine you notice that a person you don't know is looking at you. You suddenly find yourself feeling unsettled.

A. Feeling this unsettled means this person intends to do me harm.
B. I wonder why I feel this unsettled,

I am most likely to think: (please circle A, B, or C)

could this mean this person is thinking bad things about me.
C. Being looked at can make people feel unsettled, I don't worry about it.

25. Imagine that one evening you are sitting at home alone when a door suddenly slams by itself in another room.

I am most likely to think: (please circle A, B, or C)

A. Someone or something must have gotten into the house.
B. I wonder if somebody or something's there.
C. It's probably a draught.

26. Imagine someone you know calls you just as you were thinking about them. As you pick up the phone, you suddenly realise you are feeling upset.

I am most likely to think: (please circle A, B, or C)

A. It's odd that I should feel upset, but I don't read too much into it.
B. I wonder why I feel upset, could there be something peculiar about this call.
C. Feeling upset means something, it must be bad news.

27. Imagine you are walking down the road when you suddenly notice a careers poster which seems to stand out from your surroundings.

I am most likely to think: (please circle A, B, or C)

A. I wonder why my eyes seem drawn to that poster.
B. Maybe I'm noticing it because my career isn't such a success.
C. It's a sign that my life is such a failure.

28. Imagine you are on a bus; the bus driver keeps stopping abruptly, so that you stumble each time.

I am most likely to think: (please circle A, B, or C)

A. I wonder if he's doing it on purpose to wind people up.
B. This bus driver can't drive properly.
C. He's doing it on purpose to humiliate me.

29. Imagine you hear that a friend is having a party and you have not been invited.

I am most likely to think: (please circle A, B, or C)

A. I wonder if they don't like me as much as I thought they did.
B. Perhaps I can try to find out a bit more about the situation before making any assumptions.
C. They obviously don't like me.

30. Imagine you are dozing on the sofa in front of the TV and you suddenly wake up startled.

I am most likely to think: (please circle A, B, or C)

A. I tend to always wake up startled when I'm dozing.
B. The TV must have woken me.
C. I can never get any sleep.

Beck Cognitive Insight Scale

Below is a list of sentences about how people think and feel. Please read each sentence in the list carefully. Indicate how much you agree with each statement by circling the number in the corresponding space in the column next to the statement.

	Do not agree at all.	**Agree slightly**	**Agree a lot.**	**Agree completely**
1. At times, I have misunderstood people's attitudes towards me.	0	1	2	3
2. My interpretations of my experiences are definitely right.	0	1	2	3
3. Other people can understand the cause of my unusual experiences better than I can.	0	1	2	3
4. I have jumped to conclusions too fast.	0	1	2	3
5. Some of my experiences that have seemed very real may have been due to my imagination.	0	1	2	3
6. Some of the ideas I was certain were true turned out to be false.	0	1	2	3
7. If something feels right, it means that it is.	0	1	2	3
8. Even though I feel strongly that I am right, I could be wrong.	0	1	2	3
9. I know better than anyone else what my problems are.	0	1	2	3
10. When people disagree with me, they are generally wrong.	0	1	2	3
11. I cannot trust other people's opinions about my experience.	0	1	2	3
12. If somebody points out that my beliefs are wrong, I am willing to consider it.	0	1	2	3

13. I can trust my own judgement at all times.	0	1	2	3
14. There is often more than one possible explanation for why people act the way they do.	0	1	2	3
15. My unusual experiences may be due to my being extremely upset or stressed.	0	1	2	3

Recovery Assessment Scale

I am going to read a list of statements which people sometimes use to describe themselves and their lives. Please listen carefully to each one and indicate the response that best described the extent to which you agree or disagree with the statement. For each of these statements, please indicate whether you strongly disagree (1), disagree (2), not sure (3), agree (4), or strongly agree (5) with these statements.

	Strongly disagree	**Disagree**	**Not sure**	**Agree**	**Strongly agree**
1. I have a desire to succeed	1	2	3	4	5
2. I have my own plan for how to stay or become well.	1	2	3	4	5
3. I have goals in life that I want to reach.	1	2	3	4	5
4. I believe I can meet my current personal goals.	1	2	3	4	5
5. I have a purpose in life.	1	2	3	4	5
6. Even when I don't care about myself, other people do.	1	2	3	4	5
7. I understand how to control the symptoms of my mental illness.	1	2	3	4	5
8. I can handle it if I get sick again.	1	2	3	4	5
9. I can identify what triggers the symptoms of my mental illness.	1	2	3	4	5
10. I can help myself become better.	1	2	3	4	5
11. Fear doesn't stop me from living the way I want to.	1	2	3	4	5
12. I know that there are mental health services that do help me.	1	2	3	4	5

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
13. There are things that I can do that help me deal with unwanted symptoms.	1	2	3	4	5
14. I can handle what happens in my life.	1	2	3	4	5
15. I like myself.	1	2	3	4	5
16. If people really knew me, they would like me.	1	2	3	4	5
17. I am a better person than before my experience with mental illness.	1	2	3	4	5
18. Although my symptoms may get worse, I know I can handle it.	1	2	3	4	5
19. If I keep trying, I will continue to get better.	1	2	3	4	5
20. I have an idea of who I want to become.	1	2	3	4	5
21. Things happen for a reason.	1	2	3	4	5
22. Something good will happen eventually.	1	2	3	4	5
23. I am the person most responsible for my own improvement.	1	2	3	4	5
24. I'm hopeful about my future.	1	2	3	4	5
25. I continue to have new interests.	1	2	3	4	5
26. It is important to have fun.	1	2	3	4	5
27. Coping with my mental illness is no longer the main focus of my life.	1	2	3	4	5

	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
28. My symptoms interfere less and less with my life.	1	2	3	4	5
29. My symptoms seem to be a problem for shorter periods each time they occur.	1	2	3	4	5
30. I know when to ask for help.	1	2	3	4	5
31. I am willing to ask for help.	1	2	3	4	5
32. I ask for help, when I need it.	1	2	3	4	5
33. Being able to work is important to me.	1	2	3	4	5
34. I know what helps me get better.	1	2	3	4	5
35. I can learn from my mistakes.	1	2	3	4	5
36. I can handle stress.	1	2	3	4	5
37. I have people I can count on.	1	2	3	4	5
38. I can identify the early warning signs of becoming sick.	1	2	3	4	5
39. Even when I don't believe in myself, other people do.	1	2	3	4	5
40. It is important to have a variety of friends.	1	2	3	4	5
41. It is important to have healthy habits.	1	2	3	4	5

Appendix I Factor structure of the PANSS used in study

Five factor model (Rodriguez-Jiminez et al., 2013)	**Pentagonal model (White et al., 1997)**
Positive Factor	**Positive Factor**
P1 Delusions	P1 Delusions
G9 Unusual thought content	G9 Unusual thought content
P3 Hallucinatory Behaviour	P5 Grandiosity
P5 Grandiosity	P3 Hallucinatory behaviour
Negative Factor	G1 Somatic Concern
N3 Poor rapport	**Negative Factor**
N1 Blunted affect	N6 Lack of spontaneity
N2 Emotional withdrawal	N1 Blunted affect
N6 Lack of spontaneity	N2 Emotional withdrawal
N4 Passive / apathetic social withdrawal	N3 Poor rapport
G7 Motor retardation	N4 Passive / apathetic social withdrawal
Disorganised / Concrete (Cognition) Factor	G7 Motor retardation
N5 Difficulty in abstract thinking	G5 Mannerisms and posturing
P2 Conceptual disorganisation	G8 Uncooperativeness
G11 Poor attention	G13 Disturbance of volition
Excited Factor	G14 Poor impulse control
P4 Excitement	**Disorganised / autistic preoccupation**
G14 Poor impulse control	G11 Poor attention
P7 Hostility	G15 Preoccupation
G8 Uncooperativeness	N5 Difficulty in abstract thinking
Depressed Factor	N7 Stereotyped thinking
G3 Guilt feelings	G13 Disturbance of volition
G6 Depression	P3 Hallucinatory behaviour
G2 Anxiety	**Excited / activation**
	P7 Hostility
	G14 Poor impulse control
	P4 Excitement
	G8 Uncooperativeness
	N3 Poor rapport
	G4 Tension
	Dysphoric mood / Emotional distress
	G2 Anxiety
	G4 Tension
	G3 Guilt feelings
	G6 Depression
	G1 Somatic concern

Appendix J Author Guidelines for Journal of Clinical Psychology

13. Journal of Clinical Psychology

Edited By: Timothy R. Elliott (Editor) and Barry A. Farber (In Session)

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2. Manuscript Preparation

Format . Number all pages of the manuscript sequentially. Manuscripts should contain each of the following elements in sequence: 1) Title page 2) Abstract 3) Text 4) Acknowledgments 5) References 6) Tables 7) Figures 8) Figure Legends 9) Permissions. Start each element on a new page. Because

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Results: Succinctly report the results that pertain to the expressed objective(s).

Conclusions: State the important conclusions and implications of the findings.

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